

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF ARIZONA

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In Re: Bard IVC Filters ) MD-15-02641-PHX-DGC  
Products Liability Litigation )  
 ) Phoenix, Arizona  
 ) March 26, 2018  
 )  
\_\_\_\_\_  
Sherr-Una Booker, an individual, )  
 )  
Plaintiff, )  
 ) CV-16-00474-PHX-DGC  
v. )  
 )  
C.R. Bard, Inc., a New Jersey )  
corporation; and Bard Peripheral )  
Vascular, Inc., an Arizona )  
corporation, )  
 )  
Defendants. )  
\_\_\_\_\_

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 8 A.M. SESSION

(Pages 1595 - 1731)

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Proceedings Reported by Stenographic Court Reporter  
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**P R O C E E D I N G S**

(Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Thank you. Please be seated.

Morning, everybody.

MR. LOPEZ: Morning.

MR. NORTH: Morning.

THE COURT: Counsel, one of the things we were going to talk about this morning is the discussion you all were to have about redaction of documents. Where are we on that issue?

MS. MATARAZZO: Morning, Your Honor. We're still going back and forth on a few of them, but we've got agreement on the majority at this point. So hopefully by the end of the day we'll have either agreement on it or something for you at 8:30 tomorrow that is very narrow in terms of a few we don't have agreement on.

THE COURT: Great. Okay.

You know what I would suggest, if there are areas where you end up with disagreement, that we -- if it's simple enough we can talk through it, that's fine. But if there's a number of documents for me to review, I'd suggest we have you get me a copy of the document with the section that one side or the other thinks needs to be highlighted -- I'm sorry,

08:32:20 1 deleted, have that section highlighted. And then we can just  
2 talk through them one at a time.

3 MS. MATARAZZO: That makes sense to us, Your Honor.

4 I think there may be a few today that we would also  
08:32:32 5 have the same issue that we would say would be admitted  
6 subject to discussions about hearsay within hearsay in the  
7 documents, so just to let you know that may come up few times  
8 today as well.

9 THE COURT: Okay.

08:32:46 10 MS. MATARAZZO: We'll work through it with them,  
11 yeah. Thank you.

12 THE COURT: All right. I received your briefs you  
13 filed on the FDA warning letter. I've not had a chance to  
14 look at them. I will -- I don't think I'll have a chance to  
08:32:58 15 look at them over the lunch hour because I have a hearing at  
16 the end of the day I need to prepare for, but I will try to  
17 look at that tonight and give you my thoughts on that tomorrow  
18 morning.

19 What other matters do we need to address before we  
08:33:14 20 start this morning?

21 MR. LOPEZ: Two things. Maybe more. At least I know  
22 I have two things to talk to you about, Your Honor.

23 Obviously, we're trying to save time on the plaintiff  
24 side for sure. We've got some documents that we'd like to  
08:33:33 25 have counsel agree that they're authentic, we can preadmit

08:33:40 1 them so I don't have to spend a half hour with the witness.  
2 They're complaint files. They were produced by the defendant  
3 on an electronic database, and these have been printed out.  
4 And I'd like to --

08:33:55 5 Did we send them to them last night?

6 MS. SMITH: We gave it to them this morning.

7 MR. LOPEZ: Yeah, we gave it to them this morning.

8 If we could do things like that, Your Honor, before we can get  
9 to put up a witness and spend a lot of time laying a  
08:34:06 10 foundation for documents that pretty clearly are business  
11 records. These are complaint files that have been produced by  
12 the defendant.

13 THE COURT: Well, have you talked about that?

14 MR. LOPEZ: I think --

08:34:15 15 Didn't you show it to them this morning?

16 MS. SMITH: Yes.

17 MR. LOPEZ: They're probably not going to be used  
18 today, but they might be. So I'd ask counsel to take a look  
19 at these before we get up to put on a witness and just -- all  
08:34:29 20 he has to do is confirm that these are the complaint files  
21 that are on the database that was produced to us. That's all  
22 they need to -- and they -- we even gave them a list.

23 THE COURT: Well, you all need to talk. If you can  
24 reach agreement on it, that's great. If you can't, I'll be  
08:34:44 25 happy to hear what the arguments are, but it seems to me at

08:34:48 1 this point you need to talk about whether that is agreeable to  
2 both sides.

3 MR. LOPEZ: All right.

4 The other thing, Your Honor, is we were kind of  
08:34:57 5 surprised last week when we found out that Ms. O'Quinn worked  
6 at a company where one of the juror's daughters works. And it  
7 was not disclosed to us before trial. I just -- there's  
8 nothing we can do about it now. But if the defense has any  
9 other situations like that where one of their witnesses is  
08:35:21 10 somehow -- has some kind of even a distant affiliation with  
11 one of the jurors, we'd sure like to know that before the  
12 witness takes the stand.

13 THE COURT: Well, you're talking about W.L. Gore?

14 MR. LOPEZ: Yes. I think she said she was the vice  
08:35:40 15 president. I don't even know who his daughter even works  
16 for -- in the same department --

17 THE COURT: Well, her name, I assume, was on the  
18 witness list that was given to all the jurors when they were  
19 asked --

08:35:52 20 MR. LOPEZ: Just the name. I mean, we didn't know  
21 where she worked.

22 THE COURT: Are you suggesting I should take some  
23 action on that?

24 MR. LOPEZ: Well, I don't know. I mean, I don't want  
08:36:05 25 to stop the trial. For sure I don't want to ask for a



08:36:08 1 mistrial, other than the fact that stuff like that could end  
2 up being prejudicial to us. So I just don't want it to happen  
3 again.

08:36:22 4 One of the things we thought of, Your Honor, I don't  
5 want the juror to think that, well, the plaintiff's lawyers  
6 don't trust me, or I'm being questioned. Maybe it's a  
7 situation where you can make some inquiry without -- because  
8 you heard it and not because one of the parties objected to  
9 it. But I would sure like to find out whether or not, because  
08:36:43 10 of that relationship, that that would -- pretty important  
11 witness for them. She was on the stand for three hours and  
12 said a lot of things in the defense case.

13 I don't know -- I forget what number he was, but the  
14 gentleman in the second row on the right. Whether or not that  
08:37:01 15 is having an influence on him because that is his daughter's  
16 boss. I mean, I don't know.

17 So I think that at this point we ought to think about  
18 it maybe together what would be the best thing to not have a  
19 situation where we now have a juror that is concerned or  
08:37:18 20 influenced by something that he heard on Friday about a  
21 witness that we didn't know anything about.

22 THE COURT: Did her work for Gore come out in her  
23 deposition?

24 MR. LOPEZ: Oh, her deposition was taken four years  
08:37:35 25 ago, and she was working for a completely different company.

08:37:38 1 THE COURT: Mr. North?

2 MR. NORTH: Your Honor, he's correct as to the  
3 depositions, that she was working somewhere else at the time.  
4 And I apologize for that, Your Honor. I was -- I thought  
08:37:49 5 about that right as I was doing direct, and I purposefully  
6 phrased my question, "What do you do now," and I did -- tried  
7 not to ask her where she worked, but she just -- it came out,  
8 what I think was a natural response on her part.

9 My recollection from the juror during voir dire is  
08:38:09 10 that his daughter worked in some sort of scientific role,  
11 research and development, I'm not sure, but he was shown the  
12 witness list. She was on there. He clearly did not know her.  
13 I'm afraid that we're going to just create a problem if we  
14 voir dire or do anything at this point further about that one  
08:38:33 15 comment that Ms. O'Quinn made.

16 THE COURT: Traci.

17 (The Court and the courtroom deputy confer.)

18 THE COURT: It's the fellow on the right on the back  
19 row?

08:38:57 20 MR. LOPEZ: Yes, Your Honor.

21 (The Court and the courtroom deputy confer.)

22 THE COURT: All right. Well --

23 MR. LOPEZ: Can I say just one more thing,  
24 Your Honor?

08:39:49 25 THE COURT: Yes.

08:39:51 1 MR. LOPEZ: First of all, I mean -- I'm not sure --  
2 I'm just going to say what's on my mind. I don't think that  
3 was any more an inadvertent error than her blurting out --

4 THE COURT: Mr. Lopez, let's not talk about what you  
08:40:05 5 think the other side had in their mind. We've got enough  
6 here. We need to address it.

7 MR. LOPEZ: I won't.

8 Here's the thing. What I just heard from Mr. North  
9 was we don't want to speculate. And what we do know is that  
08:40:13 10 the daughter works in a scientific role.

11 THE COURT: Okay. Let me -- because we're short on  
12 time, let me --

13 MR. LOPEZ: I wanted to make one more motion. I want  
14 to move to strike Ms. Allen's testimony.

08:40:23 15 THE COURT: I'm not going to strike her testimony.  
16 It's clearly not warranted for this kind of an issue. That's  
17 not even close, in my judgment.

18 What I can do, if you all think it's a good idea, is  
19 I can call in Juror Number 5, that's his number now, he was  
08:40:39 20 Juror 26 at the time of jury selection, and tell him that my  
21 notes reflect, which they do, his daughter works for Gore, we  
22 had a witness who worked for Gore, and ask him a few questions  
23 about whether that will affect in any way his ability to be a  
24 fair and impartial juror, ask whether he has any knowledge of  
08:40:59 25 this witness or whether she has any relationship with his

08:41:03 1 daughter, and see how he answers the questions.

2 And if there's any concerns based on how he responds,  
3 then I'll hear you in terms of what we ought to do. But I'm  
4 happy to do that this morning to address the issue.

08:41:20 5 MR. LOPEZ: Yes, Your Honor. Excuse me. Yes,  
6 Your Honor. I think we should do that. Or you should do  
7 that.

8 THE COURT: From the defense standpoint, what are  
9 your thoughts?

08:41:31 10 MR. NORTH: I still believe that it's probably not  
11 necessary because it was such a fleeting reference, but I'm  
12 certainly not going to object if the Court thinks that's  
13 appropriate.

14 THE COURT: All right. I will do that. We will do  
08:41:45 15 that before we get started this morning.

16 But then what's going to happen is he's going to be  
17 called out of the jury room without the rest of the jurors,  
18 and they're going to know that. And what I would recommend is  
19 that I tell him that when they ask him why did you get called  
08:42:01 20 into court, he simply say the Judge had a follow-up question  
21 from the voir dire on the first day of trial that he wanted to  
22 ask me, and that he not talk to them about the fact that his  
23 daughter works at the company that one of the witnesses is  
24 from. That way we don't create a process of speculation  
08:42:21 25 within the jury itself.

08:42:23 1 Any thoughts on that?

2 MR. LOPEZ: That's fine.

3 So are we going to be here, too, Judge, when you do  
4 that?

08:42:30 5 THE COURT: Yeah.

6 Do you have another comment?

7 MR. LOPEZ: No. I think we -- you need to inquire --  
8 the only thing there is if there's anything else like that  
9 that might be coming, we'd like a heads-up.

08:43:06 10 THE COURT: Yeah, obviously we should know that ahead  
11 of time from both sides if there's any issue coming.

12 Mr. O'Connor?

13 MR. O'CONNOR: Yes, Your Honor. Later on today may  
14 be a better time. I just want to bring to the Court's

08:43:17 15 attention, before Dr. Paul Briant testifies, he's an expert  
16 engineer for the defense, on two exhibits they intend to bring  
17 through him. One is a summary of his opinions, which I think  
18 are hearsay, but I also think they're not accurate and they  
19 just elevate what he's going to say, but -- and the other one  
08:43:36 20 is Exhibit 5874, which was not on his reliance list and is  
21 something he never talked about in his report.

22 MR. NORTH: Which one?

23 MR. O'CONNOR: It's 5874. This one here, if you want  
24 to see it.

08:44:00 25 MR. NORTH: He's not talking about that.

08:44:02 1 MR. O'CONNOR: That's not coming in?

2 MR. NORTH: No.

3 MR. O'CONNOR: All right.

4 Then the other one, Your Honor, is just Exhibit 7809,

08:44:08 5 which is an opinion summary that, first of all, is hearsay;

6 secondly it's really akin to putting in a report that wasn't

7 written in this case.

8 THE COURT: What's the number?

9 MR. O'CONNOR: It is Exhibit 7809.

08:44:25 10 THE COURT: What is the intent with that exhibit?

11 MR. NORTH: Your Honor it is purely a demonstrative

12 exhibit. It was prepared by him, the witness himself, much

13 like Dr. Tillman had a demonstrative summarizing her opinions.

14 We would propose to utilize it the same way we did with

08:44:44 15 Dr. Tillman, which would be to have him recite his opinions

16 first without this, and then ask if he prepared a chart or a

17 demonstrative that summarizes the opinions, and show it to the

18 jury at that time.

19 THE COURT: Do you have a copy?

08:44:56 20 MR. NORTH: I do, Your Honor.

21 May I approach?

22 THE COURT: Yes.

23 So explain, Mr. O'Connor, what your objections are to

24 this exhibit.

08:45:59 25 MR. O'CONNOR: Yes, Your Honor. So what I understand

08:46:01 1 is from Ms. Tillman, her statements came directly from her  
2 report. If you just look at the first statement here, he says  
3 "incorporates unrealistic biased assumptions." Those aren't  
4 words that he used. He used "overly simplistic" and "overly  
08:46:18 5 conservative" in his report.

6 And, you know, this really does call for -- it's in a  
7 form almost a legal conclusion, but it just elevates the  
8 opinions that he never put in his report.

9 THE COURT: And what exactly are those opinions that  
08:46:31 10 aren't in the report?

11 MR. O'CONNOR: And I don't have the report. They  
12 were long, extensive reports. But he said that  
13 Dr. McMeeking's assumptions were overly simplistic and overly  
14 conservative. Here is what he's saying, is they're  
08:46:45 15 unrealistic and biased assumptions. Those are terms he never  
16 used in his report.

17 THE COURT: Did he use those terms in his report,  
18 Mr. North?

19 MR. NORTH: I'm looking right now for those exact  
08:46:55 20 terms, Your Honor. He certainly criticized the assumptions in  
21 great detail. But I will find that.

22 Your Honor, it's going to take me a while. He has a  
23 very lengthy section.

24 He does say, as Mr. O'Connor said, that the analyses  
08:47:45 25 performed by Dr. McMeeking to reach his conclusions are

08:47:47 1       simplistic, inaccurate, and overly conservative and therefore  
2       do not provide a reliable assessment of the strains in Bard's  
3       filters.

4               THE COURT: Do they say they're biased?

08:47:58 5               MR. NORTH: I'm going to have to continue looking for  
6       that, Your Honor, whether that word is used.

7               THE COURT: And the drawing that is on this sheet, is  
8       this somehow a demonstrative he's going to use?

9               MR. NORTH: Yes. The drawing shows how he, in his  
08:48:13 10       testing, tested the entire filter, as opposed to Dr. McMeeking  
11       testing only one arm.

12              THE COURT: And the illustration on the right, is  
13       that -- that's an illustration of what Dr. McMeeking did? Is  
14       that the idea --

08:48:33 15              MR. NORTH: Right. How he tested just one arm as  
16       opposed to the entire filter.

17              THE COURT: Do you have an objection to the  
18       demonstrative on the right?

19              MR. O'CONNOR: Well, I would agree that he has  
08:48:41 20       testified to that. And to the extent that Dr. McMeeking used  
21       illustrations, I wouldn't have an objection to that. I'm more  
22       concerned about the words.

23              And then I have one more quick issue on him.

24              THE COURT: It looks like it's the first bullet point  
08:48:57 25       that you're most concerned about; is that right?



08:48:59 1 MR. O'CONNOR: That's the most concern.

2 And then, I think -- I don't think -- oh --

3 MR. NORTH: Your Honor, we can just short-circuit  
4 this. I mean, we're not hung up on the word "biased." We can  
08:49:12 5 just take it out and just say "unrealistic assumptions,"  
6 because I think the wording he used fairly incorporates the  
7 concept of unrealistic.

8 MR. O'CONNOR: Well, you know, I think unrealistic is  
9 taken out of context the way Dr. Briant put it in his report.  
08:49:30 10 And, again, I just think that this is just perpetuating a  
11 report in a way that it would never have come in.

12 THE COURT: Well, this isn't coming into evidence.

13 MR. O'CONNOR: I understand that. I understand that.  
14 But this is certainly things that weren't in his report.

08:49:42 15 The other area, he says "published studies." I'm  
16 only aware that he really referred to two studies, a Laborda  
17 study on anatomy or the *in vivo* stresses and strains, and a  
18 Murphy report, and this is kind of an overbroad statement for  
19 this jury to hear that somehow both these experts went through  
08:50:06 20 elaborate medical reports. That's really just not accurate.

21 THE COURT: That sounds like fair ground for  
22 cross-examination.

23 MR. O'CONNOR: I agree.

24 THE COURT: Let's have you reword the first bullet  
08:50:17 25 point.

08:50:17 1 MR. NORTH: Okay.

2 THE COURT: Let's have you replaced "unrealistic and  
3 biased" with "incorrect."

4 MR. NORTH: Okay.

08:50:21 5 THE COURT: That is a nice neutral term that conveys  
6 the same idea.

7 And then, when he gets into the more detailed  
8 explanation, you'll be able to cross-examine him on that,  
9 Mr. O'Connor.

08:50:30 10 And with that change, I'll allow this demonstrative  
11 to be used.

12 MR. O'CONNOR: One more quick point. Dr. Briant  
13 testified in deposition that for this MDL, Exponent and him  
14 have billed \$545,000. The defense has made a big deal about  
08:50:47 15 our experts and their costs. I want to bring that out, but I  
16 don't want to draw an objection that somehow that gets into  
17 the other cases or the other litigation. I don't know how to  
18 handle it, but it is clear that is a steep figure, and I think  
19 it is important for the jury to hear that the defense is  
08:51:02 20 paying steep figures for the their experts in view of the  
21 position they've taken against ours.

22 THE COURT: Any objection to that, Mr. North?

23 MR. NORTH: Your Honor, I think that's fair  
24 cross-examination.

08:51:13 25 THE COURT: I think it is as well, but, as you know,

08:51:15 1 as we've talked before, ask the question in a way that doesn't  
2 allude to other cases. Just that he and his firm have been  
3 compensated in connection with his opinions in this case.

4 MR. O'CONNOR: All right. Thank you.

08:51:29 5 THE COURT: Okay. Are there other matters we need to  
6 take up?

7 MR. NORTH: Your Honor, all I would mention is at  
8 some point I would like to make my Rule 50 motion, even if  
9 very briefly. I was thinking we might be able to do that  
08:51:43 10 tomorrow when we discuss jury instructions.

11 THE COURT: That's fine. Let's do it then.

12 And, as you know, that ruling is as of the time of  
13 the defendant resting. That's the point in time where the  
14 evidence is evaluated.

08:51:55 15 Okay. Traci, would you go see if Juror 5 is here.

16 THE COURTROOM DEPUTY: Um-hmm.

17 THE COURT: Folks, if you would stand up for Juror 5,  
18 please.

19 (Juror Number 5 entered the courtroom.)

08:52:54 20 THE COURT: Good morning.

21 Go ahead and be seated.

22 Juror 5, you can have a seat.

23 I wanted to ask you a question this morning in light  
24 of some evidence that came in last week.

08:53:05 25 JUROR NUMBER 5: Sure.

08:53:05 1 THE COURT: There was a witness by the name of  
2 Ms. O'Quinn who testified, and she testified that she is now  
3 an officer of Gore, a manager at Gore.

4 JUROR NUMBER 5: Right.

08:53:15 5 THE COURT: And my notes reflect you have a daughter  
6 who works for Gore.

7 JUROR NUMBER 5: Yes.

8 THE COURT: Would the fact your daughter works for  
9 Gore and Ms. O'Quinn works for Gore have any effect upon your  
08:53:26 10 ability to be a fair witness in this case -- or a fair juror  
11 in this case?

12 JUROR NUMBER 5: No.

13 THE COURT: Would it in any way influence how you  
14 evaluate her testimony in the case?

08:53:36 15 JUROR NUMBER 5: No.

16 THE COURT: Would you lean more in her favor because  
17 of the fact that she's at the same firm your daughter's at?

18 JUROR NUMBER 5: No.

19 THE COURT: Did anything she say suggest to you that  
08:53:46 20 she's got any kind of a connection with your daughter in terms  
21 of managing her or working in the same department or anything  
22 like that?

23 JUROR NUMBER 5: Not at all.

24 THE COURT: Okay. So you're satisfied you can remain  
08:53:59 25 completely fair and impartial notwithstanding that fact?

08:54:03 1 JUROR NUMBER 5: Yes.

2 THE COURT: Okay.

3 Counsel, do you have any follow-up questions for  
4 Juror Number 5?

08:54:09 5 MR. LOPEZ: We don't Your Honor. Thank you.

6 MR. NORTH: Nothing, Your Honor.

7 THE COURT: Okay.

8 Juror Number 5, your fellow jurors are going to  
9 wonder why you were called into the courtroom. If they ask  
08:54:18 10 you or if you want to tell them, just tell them that I had a  
11 follow-up question for you from the first day of voir dire  
12 that occurred to me. But don't mention Ms. O'Quinn or the  
13 connection to her. We're just -- we're not only trying to  
14 avoid actual bias, but the appearance of any kind of bias, and  
08:54:38 15 so we try to keep these things as neutral as we can. So you  
16 can certainly tell them I had a follow-up question for you  
17 based on the voir dire, and that should let them know that  
18 you're not in some kind of trouble.

19 JUROR NUMBER 5: Okay.

08:54:50 20 THE COURT: Okay. Thank you, sir.

21 JUROR NUMBER 5: You're welcome.

22 (Juror Number 5 exited the courtroom.)

23 THE COURT: All right. Thank you.

24 Be seated.

08:55:03 25 I want to note for the record that I'm satisfied by

08:55:06 1 the manner in which Juror Number 5 answered the questions that  
2 this is not going to influence him. I think he remains fair  
3 and impartial.

4 I probably should have waited to say that until after  
08:55:18 5 I heard if you all have any arguments to the contrary.

6 Do you have any concerns after hearing those answers?

7 MR. LOPEZ: No. I think he answered the questions  
8 appropriately. Thank you for doing that, Your Honor.

9 THE COURT: All right.

08:55:28 10 MR. NORTH: No concerns, Your Honor.

11 THE COURT: Okay. All right.

12 Anything else we need to address?

13 MS. REED ZAIC: Your Honor, I just want to point out  
14 in like the last 30 seconds, it was actually a little  
08:55:38 15 difficult to hear you. We were all sort of leaning in to --  
16 you explained the acoustics are difficult, and I think you  
17 just --

18 THE COURT: All right. This mic is not always great.  
19 We'll turn it up a little bit.

08:55:50 20 Okay. So where are we starting this morning in terms  
21 of the evidence?

22 MR. NORTH: Your Honor, we will be calling Mr. John  
23 Van Vleet to the stand.

24 THE COURT: Okay.

08:56:07 25 Traci, do we have all the jurors?

DIRECT EXAMINATION - JOHN VAN VLEET

08:56:13 1 THE COURTROOM DEPUTY: I think so.

2 THE COURT: All the jurors are here. So unless we  
3 need a break for any reason, we'll just get them in and get  
4 started. Is that all right?

08:56:18 5 Okay. Let's do that.

6 (The jury entered the courtroom at 8:56.)

7 THE COURT: Please be seated.

8 Good morning, ladies and gentlemen. Welcome back.  
9 Thanks for being here this morning.

08:58:08 10 We are going to continue with another witness this  
11 morning.

12 Mr. North.

13 MR. NORTH: Thank you, Your Honor. At this time the  
14 defendants would call Mr. John Van Vleet to the stand.

08:58:21 15 THE COURTROOM DEPUTY: If you would please come  
16 forward, stand right here and raise your right hand.

17 **JOHN VAN VLEET,**  
18 called as a witness herein, after having been sworn or  
19 affirmed, was examined and testified as follows:

20 THE COURTROOM DEPUTY: Sir, could you spell your last  
21 name.

22 THE WITNESS: Sure. It's V-A-N, capital V, L-E-E-T.

23 D I R E C T E X A M I N A T I O N

24 BY MR. NORTH:

08:59:06 25 Q Good morning, Mr. Van Vleet.

DIRECT EXAMINATION - JOHN VAN VLEET

08:59:08 1 A Good morning.

2 Q Were you formerly employed by Bard?

3 A Yes.

4 Q And how long did you work with Bard?

08:59:15 5 A Ten and a half years.

6 Q What division of Bard did you work for?

7 A Bard Peripheral Vascular.

8 Q What was your title at Bard?

9 A Vice president regulatory affairs and clinical programs.

08:59:27 10 Q And what sorts of products did you work with while at

11 Bard?

12 A All of the Bard Peripheral Vascular family of products,

13 including angioplasty, balloon stents, covered stents, biopsy

14 products, inferior vena cava filters. Probably missing

08:59:43 15 something. Vascular grafts.

16 Q What were your responsibilities as the vice president of

17 regulatory affairs and clinical programs?

18 A I was responsible for registering all of our products

19 globally, U.S. and otherwise, with the ministries of health,

08:59:57 20 FDA in this country, Health Canada, et cetera. And I was also

21 responsible for designing and conducting clinical trials that

22 would be required to support those registrations.

23 Q And did Bard itself operate clinical trials on occasion?

24 A Yes.

09:00:16 25 Q What sorts of clinical trials did you work on during your



## DIRECT EXAMINATION - JOHN VAN VLEET

09:00:19 1 decade with Bard?

2 A So they're called investigational device exemption trials.  
3 They're for products that have yet to be marketed in the  
4 United States.

09:00:32 5 We studied stents, covered stents, valvuloplasty  
6 balloon, IVC filters.

7 Q During the course of your work at Bard, did you have  
8 interactions with the FDA on occasion?

9 A Yes. Very frequently.

09:00:49 10 Q What sorts of interactions would you have with the FDA?

11 A So we would have telephone conversations, e-mail  
12 exchanges, face-to-face meetings. Correspondence.

13 Q Mr. Van Vleet, did you grow up in this country?

14 A No. I was born and raised in San Juan de la Maguana, it's  
09:01:09 15 a little village in the Dominican Republic, about 50 miles  
16 from the Haiti border. My parents were missionaries there.

17 Q Did you come to the states to go to college?

18 A I did. I graduated high school and came out to the  
19 states.

09:01:26 20 Q Tell us about your educational background.

21 A Sure. I have a bachelor of science degree from Purdue.  
22 Major in biology, minor in chemistry. I completed a year of  
23 clinical internship and am licensed as a medical technologist.  
24 And then, I have a master's degree in basically business  
09:01:44 25 administration.

## DIRECT EXAMINATION - JOHN VAN VLEET

09:01:46 1 Q Do you have any board certifications or licenses?

2 A Yes. I hold a license as a medical technologist through  
3 the American Society of Clinical Pathologists.

4 Q And what does that involve as a medical technologist  
09:01:59 5 through the American Society of Clinical Pathology?

6 A Sure. It's a license to practice laboratory medicine in a  
7 hospital or health care setting.

8 Q Now, when did you first start working in the medical  
9 device industry?

09:02:17 10 A In October of 1988.

11 Q And why have you devoted your career to the field of  
12 medical devices?

13 A It's a fascinating career. It allows me to combine my  
14 scientific background, my years of working in the clinical and  
09:02:34 15 hospital environment, and also care for patients.

16 Q When you were working at Bard, when did you first become  
17 involved with IVC filters?

18 A Immediately upon my employment in June of 2007.

19 Q And what was your involvement at the beginning with IVC  
09:03:03 20 filters?

21 A My involvement was primarily on the clinical side, is to  
22 understand the conduct of the clinical trials that were  
23 ongoing. There were three or four -- four, four clinical  
24 trials ongoing, including an inferior vena cava filter trial  
09:03:17 25 that had just concluded, and to help prepare the clinical data

## DIRECT EXAMINATION - JOHN VAN VLEET

09:03:21 1 for submission to the FDA.

2 Q Now, did I understand correctly that you began working at  
3 Bard in 2008?

4 A 2007.

09:03:32 5 Q 2007.

6 And do you know Shari O'Quinn? Shari Allen O'Quinn.

7 A Oh, yes. I've met her. We didn't overlap. She was there  
8 prior to me beginning.

9 Q Did you essentially take over her position once she left?

09:03:49 10 A Yes.

11 Q And the clinical trial regarding IVC filters that you  
12 referenced, is that the EVEREST trial?

13 A It is, yes.

14 Q Now, had that trial already gotten underway by the time  
09:04:07 15 you came to the company?

16 A Enrollment had completed, and I believe all of the  
17 followup had, as well, so the analysis, the data analysis was  
18 ongoing.

19 Q Over your career, Mr. Van Vleet, how many clinical trials  
09:04:24 20 have you conducted for Class II devices that go through the  
21 510(k) process?

22 A Two, at the most.

23 Q Is it unusual to have a clinical trial for a device that's  
24 going through the 510(k) clearance process?

09:04:41 25 A Yes.

## DIRECT EXAMINATION - JOHN VAN VLEET

09:04:42 1 Q And why is that?

2 A Generally speaking, Class III devices are considered more  
3 high-risk devices, and the process of evaluation on the part  
4 of the FDA in nearly every case requires human clinical data.

09:05:00 5 On the Class II side, the FDA develops what is called  
6 performance standards, mostly testing in bench environments or  
7 in animals, perhaps, but very rarely do you have human  
8 clinical data submitted on behalf of a Class II application.

9 Q Was IVC filters one of those rare instances?

09:05:22 10 A Yes.

11 Q Now, you said the study was underway, the EVEREST study,  
12 when you began with the company.

13 Did you become familiar with the study as a part of  
14 your work?

09:05:32 15 A I did.

16 Q And what did you review to familiarize yourself with the  
17 status of that study?

18 A So I would review all of the applications to the FDA,  
19 including the application to conduct the clinical trial. That  
09:05:45 20 would include the clinical protocol. I would have reviewed  
21 any of the interim reports submitted to the FDA, the six- and  
22 12-month interim investigational device annual reports, and  
23 any of the analyses, any drafts of the clinical study report,  
24 and basically any correspondence surrounding that trial.

09:06:12 25 Q What was the purpose of the EVEREST study?

DIRECT EXAMINATION - JOHN VAN VLEET

09:06:14 1 A The purpose of the study was to evaluate the safety of  
2 retrievability or removability of the G2 optional filter.

3 Q Did the study look at anything to do with adverse events?

4 A It did. It collected all clinical adverse events, medical  
09:06:40 5 events over the life of the study.

6 Q Now, as a part of your work with the company in overseeing  
7 the EVEREST study, did you help to prepare any reports to the  
8 FDA?

9 A Yes. I ultimately had the responsibility to review and  
09:07:03 10 approve any documentation or any reporting that goes to the  
11 FDA.

12 Q And what would be included in those reports?

13 A So depending on the nature of the report, if it's a report  
14 about the study itself, every six months there's a listing of  
09:07:21 15 every investigational site and investigator, there's a summary  
16 of all adverse events collected in the study. Normally, the  
17 overall summary of the clinical data itself is reserved for  
18 the final submission. But the FDA does require us to submit  
19 adverse event information throughout the life of the study.

09:07:42 20 MR. NORTH: If we could see Exhibit 5335.

21 And my notes are a little off as to whether that's  
22 been admitted or not. I don't believe so.

23 THE COURT: It's 5335?

24 MR. NORTH: Right.

09:07:58 25 THE COURTROOM DEPUTY: 5335 is not admitted.

DIRECT EXAMINATION - JOHN VAN VLEET

09:08:02 1 THE COURT: We do not show it in evidence.

2 MR. NORTH: Okay.

3 BY MR. NORTH:

4 Q Do you see 5335 in front of you, Mr. Van Vleet?

09:08:11 5 A I believe it is. It says 5335.0001?

6 Q Right.

7 A Oh, yeah.

8 Q Do you recognize what that document is?

9 A Yes. This is an annual progress report on the clinical  
09:08:22 10 trial to the FDA.

11 Q And is this prepared by the team that works under you?

12 A Yes, it is.

13 Q And is this report maintained by the company in its  
14 business files?

09:08:36 15 A Yes.

16 Q And is it prepared contemporaneous with the conduct of the  
17 study?

18 A Yes.

19 MR. NORTH: Your Honor, at this time we would tender  
09:08:45 20 5335.

21 MR. LOPEZ: Your Honor, two objections. Number 1 is  
22 it's dated two months after Ms. Booker received her G2 device;  
23 and secondarily, if it's going to be admitted, I'd like it to  
24 be subject to hearsay objections within the document itself.

09:09:06 25 THE COURT: You're talking about hearsay within

DIRECT EXAMINATION - JOHN VAN VLEET

09:09:08 1 hearsay and the parties' discussion of that?

2 MR. LOPEZ: Yes, Your Honor.

3 THE COURT: All right.

4 I'm going to overrule the relevancy objection and  
09:09:14 5 admit the document subject to the parties conferring about  
6 hearsay within hearsay.

7 (Exhibit 5335 admitted.)

8 MR. NORTH: Thank you, Your Honor.

9 Could we go to page 18.

09:09:42 10 Your Honor, if we could publish this to the jury.

11 THE COURT: You may.

12 BY MR. NORTH:

13 Q Mr. Van Vleet, if I could draw your attention to the  
14 bottom of page 18.

09:09:55 15 Did the report advise the FDA as to any adverse  
16 events, including caudal migrations, that had occurred during  
17 the study?

18 A Yes, it did.

19 MR. NORTH: If we could see 5334, please.

09:10:23 20 BY MR. NORTH:

21 Q Does the FDA sometimes follow up with questions regarding  
22 any reports that you submit regarding a clinical trial?

23 A Yes. Nearly -- nearly every time.

24 Q And did they follow up with questions to the company after  
09:10:40 25 the August 7th, 2007, annual report regarding the EVEREST

DIRECT EXAMINATION - JOHN VAN VLEET

09:10:46 1 trial?

2 A They did.

3 Q And did you receive this particular letter?

4 A Yes.

09:10:53 5 Q And was this letter maintained as part of the business  
6 records for the company?

7 A It is.

8 Q And are you familiar personally with this letter?

9 A I am.

09:11:06 10 MR. NORTH: Your Honor, at this time we would tender  
11 5334.

12 MR. LOPEZ: Your Honor, same objections: The hearsay  
13 objection; after Ms. Booker's implant; as well as beyond the  
14 scope of the Court's ruling on the motions that were made  
09:11:20 15 pursuant to the *Cisson* case.

16 THE COURT: I don't understand that last objection,  
17 Mr. Lopez.

18 MR. LOPEZ: Well, do you want to talk at sidebar real  
19 quick, Your Honor?

09:11:38 20 THE COURT: If you think we need to, I can, yeah.

21 MR. LOPEZ: Well, let me just -- I can -- it doesn't  
22 relate to the 510(k) process.

23 THE COURT: Okay. That's the basis for the  
24 objection. All right.

09:11:56 25 The relevancy objection and the *Cisson* ruling



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objection are overruled. This exhibit is admitted subject to the parties' review for hearsay within hearsay.

MR. NORTH: Thank you, Your Honor.

(Exhibit 5334 admitted.)

MR. NORTH: If we could look on page 2 of this exhibit.

BY MR. NORTH:

Q In question 3, did the FDA then ask Bard concerning information regarding the reports of caudal migration in the EVEREST study?

A Yes, they did.

Q Now, did Bard respond to the FDA's inquiries?

A Yes.

MR. NORTH: If we could look at Exhibit 5336, please.

Oh, I'm sorry, could we back up to the other one.

And show that same page on 002 and question 3.

Your Honor, could we publish this to the jury?

MR. LOPEZ: I guess the signature page, Your Honor, could I look at the last page of the document?

THE COURT: I'm sorry, I couldn't hear what you said.

MR. LOPEZ: If I could just see the last page of the document.

THE COURT: This one's already in evidence.

MR. LOPEZ: Oh, I'm sorry. I thought it was a new document.

DIRECT EXAMINATION - JOHN VAN VLEET

09:13:16 1 THE COURT: He did move on, but then he came back.

2 This is 5334?

3 MR. NORTH: Yes.

4 THE COURT: Yes, you can show that page.

09:13:26 5 BY MR. NORTH:

6 Q So what did the FDA ask regarding caudal migration here?

7 A Sure. They asked specifically about the ten migrations  
8 that had been reported in the IDE annual progress report, and  
9 they asked, based on the fact that it would be a 10 percent

09:13:44 10 rate, they wanted to have an explanation about why that rate  
11 of migration would be considered clinically acceptable, and  
12 asked for additional migration rates that were reported from  
13 the currently marketed devices or the previously marketed  
14 devices compared to the migration rates in the EVEREST trial.

09:14:05 15 Q And, again, I believe you said that the company responded  
16 to the FDA's inquiries?

17 A Yes, we did.

18 MR. NORTH: If we could pull up 5336, please.

19 And could we see the last page of this.

09:14:25 20 Back up one page.

21 Okay. Let's go to the first page again, if we can.

22 BY MR. NORTH:

23 Q Do you recognize this correspondence?

24 A Yes, I do.

09:14:42 25 Q Tell us what 5336 is.

## DIRECT EXAMINATION - JOHN VAN VLEET

09:14:44 1 A So this would be the formal written response to the  
2 questions that the FDA had sent us in writing in the previous  
3 document.

4 Q And were you involved personally in crafting these  
09:14:57 5 responses to the FDA's inquiries?

6 A I was.

7 Q And is this record maintained as part of the company's  
8 business records?

9 A It is.

09:15:07 10 MR. NORTH: Your Honor, at this time we would tender  
11 5336.

12 MR. LOPEZ: No objection subject to our agreement,  
13 hearsay within hearsay.

14 THE COURT: All right. 5336 is admitted subject to  
09:15:19 15 the parties' further review for hearsay within hearsay.

16 (Exhibit 5336 admitted.)

17 MR. NORTH: If we could turn to page 13.

18 BY MR. NORTH:

19 Q Is this where --

09:15:35 20 MR. NORTH: And can we publish this to the jury,  
21 Your Honor?

22 THE COURT: You may.

23 BY MR. NORTH:

24 Q Is this where the company, Bard, started responding to the  
09:15:44 25 FDA's question 3 regarding caudal migrations?

## DIRECT EXAMINATION - JOHN VAN VLEET

09:15:47 1 A Yes, it is.

2 Q And does that go on to page 14?

3 A It does.

4 Q And to page 15?

09:15:57 5 A Yes.

6 Q All the way into 16?

7 A Yes.

8 Q Can you tell us generally, just summarize for us, what --  
9 how the company responded? What sort of information did you  
09:16:10 10 provide to the FDA regarding its inquiry?

11 A Sure. So what we attempt to do every time we receive a  
12 question from the FDA is directly address their questions and  
13 answer it.

14 The first thing, actually, that we did in this case  
09:16:26 15 was to correct the percentage of migrations that we had  
16 reported. We originally reported ten migrations out of 100.  
17 That would be obviously a 10 percent rate. But, in actuality,  
18 we had only evaluable images for 88 patients in this case, so  
19 the calculation is more around 12 percent -- 12.2 percent. So  
09:16:49 20 that was the first thing that we did, was clarify that.

21 And then we also provided them a reported rate of  
22 complaint -- complications about migrations from the  
23 commercially distributed products, like they had asked.

24 And then later on in the document, I'm not sure what  
09:17:10 25 the order of this is, but we also attempted to compare the

## DIRECT EXAMINATION - JOHN VAN VLEET

09:17:13 1 rate reported in EVEREST with the rates that we could learn  
2 about, either from other companies that were required to  
3 conduct clinical trials and we could pull this information out  
4 of their labeling, or out of published articles, just to kind  
09:17:29 5 of couch that.

6 And then, we also reminded the FDA that the Society  
7 for Interventional Radiology rate of what was in the  
8 literature --

9 MR. LOPEZ: Your Honor, I object. This is -- it  
09:17:41 10 actually is displaying, and he's now going to talk about  
11 hearsay within hearsay within hearsay in this document.

12 THE COURT: What specifically are you referring to?

13 MR. LOPEZ: Table 3, and a lot of other things on  
14 that page.

09:17:58 15 MR. NORTH: We can take it down, Your Honor.

16 THE COURT: All right. Let's take the page down, and  
17 the parties can confer about that.

18 BY MR. NORTH:

19 Q So did you report to the FDA all of the adverse events  
09:18:12 20 that occurred in the EVEREST trial?

21 A We did.

22 Q Did you receive any feedback from the FDA in response to  
23 your answers that we just saw in that exhibit?

24 A Yes. And I'm sure they either came back with more  
09:18:28 25 questions or else acknowledged that that answered the question

DIRECT EXAMINATION - JOHN VAN VLEET

09:18:32 1 that they had. I can't remember exactly right now.

2 Q Do you recall any time after receiving Bard's detailed  
3 response that the FDA expressed any concern regarding caudal  
4 migration events with the G2 filter?

09:18:50 5 MR. LOPEZ: Objection, Your Honor. Leading.  
6 "Detailed."

7 THE COURT: Sustained as leading.

8 BY MR. NORTH:

9 Q Do you recall any subsequent conversations with the FDA  
09:19:02 10 regarding caudal migration?

11 A I don't.

12 Q Did the FDA ever express concern afterward to you about  
13 caudal migration?

14 MR. LOPEZ: Objection. Hearsay.

09:19:15 15 THE COURT: Sustained.

16 BY MR. NORTH:

17 Q Did the company ever receive any further written inquiries  
18 from the FDA regarding caudal migration?

19 A Not that I can recall.

09:19:36 20 MR. LOPEZ: Objection. Hearsay.

21 THE COURT: Overruled.

22 THE WITNESS: Not that I can recall.

23 BY MR. NORTH:

24 Q Now, following this particular -- the completion of the  
09:19:47 25 EVEREST study, what were the next steps for the company with

## DIRECT EXAMINATION - JOHN VAN VLEET

09:19:50 1 the G2 after the EVEREST study was completed and all the data  
2 obtained?

3 A So the first thing that we would do is draft a clinical  
4 study report that would summarize all of the data collected in  
09:20:02 5 the study, provide additional data, in addition to what we had  
6 submitted in the annual reports, and draft an explanation of  
7 how the study was conducted. And that becomes part of the  
8 510(k) submission for the application for retrievability of  
9 the filter.

09:20:27 10 Q And were you involved in drafting the 510(k) submission  
11 based upon the EVEREST data?

12 A Yes.

13 MR. NORTH: If we could pull up 5340.

14 BY MR. NORTH:

09:20:53 15 Q And can you identify what 5340 is?

16 A Sure. It's the traditional 510(k), which is a full 510(k)  
17 for the femoral and jugular subclavian delivery kits for the  
18 G2 system, and that would be -- I believe that would be the  
19 application that includes the clinical study report on the  
09:21:19 20 EVEREST trial.

21 Q And was this prepared under your supervision?

22 A Yes.

23 Q And is this maintained as a part of the business records  
24 of the company?

09:21:31 25 A It is.

DIRECT EXAMINATION - JOHN VAN VLEET

09:21:32 1 MR. NORTH: Your Honor, at this time we would tender  
2 5340.

3 MR. LOPEZ: No objection, Your Honor, subject to our  
4 discussion regarding hearsay within hearsay.

09:21:39 5 THE COURT: All right. Admitted on that basis.

6 (Exhibit 5340 admitted.)

7 BY MR. NORTH:

8 Q As a part of this 510(k), was bench and animal testing for  
9 the G2 provided?

09:21:56 10 A It would be summarized. Since the FDA had already seen  
11 bench and animal data for the permanent indication, in some  
12 cases they ask not to have it repeated but just referenced to  
13 the previous application. I think that might have been the  
14 case here.

09:22:16 15 MR. NORTH: Let's look at 5340.0048.

16 Yeah.

17 And could we publish this to the jury, Your Honor?

18 THE COURT: You may.

19 BY MR. NORTH:

09:22:36 20 Q Did the company provide a summary here of the testing that  
21 had occurred?

22 A Yes.

23 MR. NORTH: And going over to 49.

24 Now if we could go to 61, please.

25



DIRECT EXAMINATION - JOHN VAN VLEET

09:22:56 1 BY MR. NORTH:

2 Q What sort of information in the 510(k) submission did Bard  
3 provide the FDA regarding the EVEREST study?

4 A It would provide the full clinical study report, and then  
09:23:13 5 in addition there's appendices that include what's called  
6 patient line listing. So it would be basically a summary of  
7 all of the data collected on each patient in the study.

8 MR. NORTH: If we could turn to 64.

9 Going over to 65.

09:23:34 10 BY MR. NORTH:

11 Q Did the company again provide the FDA with summary of all  
12 of the adverse events that had been reported in the EVEREST  
13 trial?

14 A Yes. Yes.

09:23:47 15 Q And did that include caudal migration?

16 A Yes.

17 MR. NORTH: If we could turn to 406 in the same  
18 exhibit.

19 BY MR. NORTH:

09:24:10 20 Q Did the company provide the FDA with a chart of those  
21 adverse events?

22 A Yes.

23 MR. NORTH: If we could blow up that chart.

24 MR. LOPEZ: Again, Your Honor, this is hearsay within  
09:24:20 25 hearsay within hearsay. And I could go on and on.

DIRECT EXAMINATION - JOHN VAN VLEET

09:24:29 1 THE COURT: Your response, Mr. North?

2 MR. NORTH: Your Honor, it is just a report to the  
3 FDA. First of all, it is not being offered for the truth of  
4 the matter asserted, just to show that there was a disclosure  
09:24:40 5 of this.

6 THE COURT: Then you agree this is subject to further  
7 discussion among the parties?

8 MR. NORTH: Yes.

9 THE COURT: All right. Let's take it down, then.

09:24:46 10 MR. NORTH: Okay.

11 BY MR. NORTH:

12 Q Were there fractures reported to the FDA as a result of  
13 the EVEREST study?

14 A Yes. I believe there was one fracture that was -- that  
09:25:04 15 occurred in the study, and that was reported to the FDA.

16 Q What about penetrations?

17 A As well.

18 Q What about tilts?

19 A Yes.

09:25:20 20 Q In your experience working with -- well, let me ask you  
21 this: Throughout your career, have you worked with regulatory  
22 and clinical affairs?

23 A Yes.

24 Q In your experience, is it customary to provide the FDA  
09:25:32 25 with this sort of detailed information regarding adverse

## DIRECT EXAMINATION - JOHN VAN VLEET

09:25:36 1 events?

2 A So in my experience, usually you would summarize the  
3 clinical data from a study in a clinical study report, which  
4 obviously this is part of, but in not all cases do you  
09:25:49 5 actually provide patient line listing that has every single  
6 data point. But it was always Bard's practice to include  
7 patient line listings with all of its trials.

8 Q What was the fracture rate in the EVEREST study, do you  
9 know?

09:26:06 10 A There was one fracture, so, again, if it's -- the  
11 denominator is considered the 100 patients in the study, it  
12 would be 1 percent.

13 Q Were the results of the EVEREST study ever published in  
14 the medical literature?

09:26:26 15 A Yes, they were.

16 Q And who was the lead author? What position was the lead  
17 author of the study published in the medical literature?

18 A Dr. Christopher Binkert.

19 MR. NORTH: If we could bring up 6892.

09:26:52 20 BY MR. NORTH:

21 Q Is 6892 a copy or a reprint of the published study in the  
22 literature?

23 A Yes, I believe it is.

24 Q And what journal was this published in?

09:27:01 25 A It's published in the journal of Vascular and

DIRECT EXAMINATION - JOHN VAN VLEET

1 Interventional Radiology. That is the official journal of the  
2 Society for Interventional Radiology.

3 Q And as a specialist in clinical affairs, are you -- do you  
4 know whether that journal is a peer-reviewed journal?

5 A It is. It is the principal peer-reviewed journal for  
6 interventional radiology.

7 Q And in the published study, did the authors also discuss  
8 the complications that had been reported in the EVEREST  
9 report?

10 A Yes.

11 Q Now, after the company submitted the 510(k) for clearance  
12 for a retrievable indication for the G2 filter, did the FDA  
13 clear the device?

14 A They did.

15 MR. NORTH: If we could look at 5339, which I believe  
16 is already in evidence.

17 THE COURT: Is that 5339?

18 MR. NORTH: Yes.

19 THE COURTROOM DEPUTY: Yes, it's in.

20 MR. NORTH: If we could display that, Your Honor?

21 THE COURT: You may.

22 BY MR. NORTH:

23 Q And can you identify what this letter is?

24 A Yes. This is the clearance letter for the retrievability  
25 indication for the G2 filter.

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09:28:42 1 Q Now, we've talked a lot about retrievability here versus  
2 permanent. At the time this letter was issued, was the G2  
3 already on the market?

4 A It was.

09:28:54 5 Q So when this new clearance letter came in January of 2008,  
6 what did that mean from a practical standpoint? What changes  
7 occurred?

8 A So we would obviously change the labeling on the device to  
9 show that we now had an indication for optional removal when  
09:29:10 10 it's no longer needed. I'm sure there was new marketing  
11 materials presented as well.

12 Q And when you say "change the labeling," what did the  
13 company do?

14 A So every device that gets cleared or approved has a label  
09:29:29 15 that's called the instructions for use, or the IFU. That is  
16 provided within every box on every device. We also provide it  
17 on our websites. And it includes all of the information about  
18 the device: The dimensions, the indications for use, the  
19 instructions for deploying it. And in the case of a device  
09:29:51 20 that has a clinical trial, you always are including a summary  
21 of that clinical trial in the instructions for use as well.

22 MR. NORTH: If we could look at Exhibit 5283, please.

23 BY MR. NORTH:

24 Q Do you recognize 5283?

09:30:18 25 A Yes, I do.

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09:30:21 1 Q And tell us what that is.

2 A Yeah, this is the updated label following the January 2008  
3 clearance of the G2 filter for retrievability, and it includes  
4 the line that says that it may be removed.

09:30:39 5 MR. NORTH: Your Honor, at this time we would tender  
6 Exhibit 5283.

7 MR. LOPEZ: Your Honor, just subject to its relevance  
8 because it is after Ms. Booker's implant.

9 THE COURT: All right. Relevancy is overruled. 5283  
09:30:54 10 is admitted.

11 (Exhibit 5283 admitted.)

12 MR. NORTH: Could we publish this to the jury,  
13 Your Honor?

14 THE COURT: You may.

09:31:03 15 MR. NORTH: Let's look over at page 2, if we could,  
16 at the very bottom right-hand corner.

17 BY MR. NORTH:

18 Q In this revised IFU of January 2008, did the company  
19 include information regarding the EVEREST study?

09:31:25 20 A Yes, we did.

21 MR. NORTH: And then if we go could go over to  
22 page 3, please. At the top left.

23 And then the paragraphs beneath that chart.

24 BY MR. NORTH:

09:31:49 25 Q Did the company outline the adverse events that had

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09:32:01 1 occurred in the EVEREST study in the instructions for use once  
2 the device was cleared for retrievability?

3 A Yes. Yes.

4 Q Did the company disclose the number of caudal migrations?

09:32:19 5 A Yes.

6 MR. NORTH: Let's look at that part when where it  
7 says "asymptomatic complications," that paragraph.

8 BY MR. NORTH:

9 Q Did the company disclose fracture?

09:32:34 10 A Yes, we did.

11 Q PE?

12 A Yes.

13 Q What does that stand for?

14 A Pulmonary embolism. That is the condition that the filter  
09:32:48 15 is trying to protect the patients from.

16 Q Tilt?

17 A Yes.

18 Q Penetration?

19 A Yes.

09:32:55 20 Q Caval occlusion?

21 A Yes.

22 Q And other complications?

23 A Yes.

24 Q Tell me this, Mr. Van Vleet, why did the company not  
09:33:04 25 reference the EVEREST trial in the instructions for use until

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09:33:07 1 January of 2008?

2 MR. LOPEZ: Foundation, Your Honor.

3 THE COURT: I think you need to lay some foundation  
4 for that, Mr. North.

09:33:13 5 BY MR. NORTH:

6 Q As the vice president of regulatory affairs, would you  
7 have been involved in any decision to revise an instructions  
8 for use?

9 A Yes.

09:33:24 10 Q Would you have played a major part in any such decision?

11 A I would have to approve any changes to labeling.

12 Q Do you recall any discussions about including EVEREST data  
13 in the instructions for use prior to 2008, January?

14 A No. Technically, that's proprietary information because

09:33:45 15 the existence of an investigational device exemption is not  
16 publicly known. And, also, FDA would consider that part of  
17 labeling or possibly part of promotional information, so they  
18 certainly would not be in favor of us doing that.

19 Q Would the FDA, in your experience, have questioned  
09:34:09 20 including the data until the device was cleared for  
21 retrievability?

22 A Yes.

23 Q And why is that?

24 A Because it could be implied --

09:34:18 25 MR. LOPEZ: I'm sorry. That calls for hearsay and



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speculation. He's asking for why -- what did the FDA do or not do something.

THE COURT: All right. Let me look at the question.

Sustained.

BY MR. NORTH:

Q What is off-label promotion?

A It's promoting a device or product for use that's outside of its label indications.

Q What would off-label promotion be with regard to a filter that had only been cleared at a point in time for permanent use?

A Any discussion of an optional indication or the ability to retrieve it would be considered off-label promotion.

Q In your experience as a regulatory professional, would it have been off-label promotion to discuss a study about retrieving the device before it had been cleared for that indication?

A Absolutely.

MR. LOPEZ: Foundation, Your Honor.

THE COURT: Overruled.

THE WITNESS: Absolutely. FDA would object to that as --

MR. LOPEZ: Objection, Your Honor. Now he's speculating as to what the FDA would do or not do.

THE COURT: Overruled.

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09:35:23 1 BY MR. NORTH:

2 Q You can --

3 A In my experience with other products, FDA would consider

4 disclosing clinical trial that is used for -- asking for an

09:35:31 5 additional indication as an attempt to imply that we already

6 had that indication. And I've had many, many cases where that

7 was the case.

8 Q Now, during your tenure with Bard, did you have occasion

9 to sit down with the FDA at a conference or a meeting to

09:35:52 10 discuss the company's, Bard's, experience with its retrievable

11 filters?

12 A Yes.

13 Q And did such a meeting take place in January of 2010?

14 A Yes.

09:36:10 15 MR. NORTH: If we could pull up 5602, please.

16 BY MR. NORTH:

17 Q Did you personally attend this meeting in 2010?

18 A I actually called for the meeting, and I did attend the

19 meeting.

09:36:30 20 Q And why did you call for a meeting with the FDA,

21 Mr. Van Vleet?

22 A There was a couple of reasons. FDA had published a safety

23 communication, and also there was an article that was first

24 presented in a conference in a cath conference, and then also

09:36:52 25 disseminated that included reports of fractures on Bard

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09:36:55 1 filters.

2 Q And did you -- who all attended this meeting from Bard?

3 A The head of quality, regulatory, and medical, the  
4 corporate head, the chief scientific and clinical officer, my  
09:37:12 5 supervisor, head of regulatory, our medical monitor, a  
6 physician, the head of quality for the division, myself, an  
7 R&D representative, quality director, my chief regulatory  
8 correspondent on this file from regulatory affairs at my  
9 division, and a contracted consultant expert in this area.

09:37:39 10 Q And was Rob Carr one of the people that attended for Bard?

11 A Yes, he was.

12 Q And did a number of people from the FDA attend this  
13 meeting?

14 A Yes. Yes. There were several people. Ten or more people  
09:37:55 15 from the FDA, including the director of the division of  
16 cardiovascular devices, the director of the vascular surgery  
17 devices branch, and safety officers and people from the office  
18 of surveillance and biometrics and their clinical reviewer. A  
19 variety of people.

09:38:18 20 Q Did you prepare a contact report regarding this meeting  
21 with the FDA?

22 A It's part of our procedure to prepare a contact report any  
23 time we have any contact with FDA, so, yes, we did.

24 Q And is that contact report usually prepared soon after a  
09:38:36 25 meeting of this nature?

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09:38:38 1 A So the FDA specifically requests us to prepare a contact  
2 report. We send it to them to ensure that they have an  
3 opportunity to comment, or if we miss something or  
4 mischaracterize something, then they correct that and send it  
09:38:50 5 back. And once it's agreed upon, then we do file it and give  
6 them a final copy. But usually that happens within two to  
7 three weeks after a -- maybe a month after, at the outside.

8 Q And then, are these contact reports maintained in the  
9 regular course of the company's business?

09:39:07 10 A Yes. They're part of our regulatory files.

11 Q Do you recall whether this particular report was sent to  
12 the FDA?

13 A Yes, it was sent to the FDA.

14 Q Do you recall whether you received any comments or  
09:39:18 15 revisions to the report from the FDA?

16 A That, I don't directly recall. But it's possible that we  
17 did. Not always do they redline it, but sometimes they do.

18 MR. NORTH: Your Honor, subject to the parties  
19 reviewing this for any hearsay within hearsay later, we would  
09:39:36 20 tender this for admission.

21 THE COURT: And this is 5602?

22 MR. NORTH: Yes.

23 MR. LOPEZ: Your Honor, I ask it not be published. I  
24 mean, every page has hearsay within hearsay within hearsay in  
09:39:49 25 it, so we need to be very careful about this one.

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09:39:52 1 THE COURT: All right. But are you objecting to it  
2 being admitted subject to your conferring on that?

3 MR. LOPEZ: No, Your Honor. Subject to our  
4 agreement.

09:40:00 5 THE COURT: All right. Exhibit 5602 is admitted  
6 subject to the parties further conferring.

7 (Exhibit 5602 admitted.)

8 BY MR. NORTH:

9 Q What did you and your team do to prepare for this meeting  
09:40:11 10 with the FDA?

11 A We typically prepare an agenda, and then we also prepare a  
12 PowerPoint or slides presentation of the information that we  
13 intend to submit to them. FDA always asks us to lay out the  
14 agenda of what they would like to discuss, what we would like  
09:40:30 15 to discuss with them. And then we also provide them a copy of  
16 the presentation prior to arriving at the FDA campus.

17 MR. NORTH: If could you pull up 5942.

18 BY MR. NORTH:

19 Q You're now looking at the cover page of 5942. Is that the  
09:40:53 20 PowerPoint presentation prepared for the meeting with the FDA?

21 A Yeah, it looks like that. I'm not sure if that's the  
22 final, but it does look like that's what we --

23 MR. NORTH: Let's look at the second page.

24 THE WITNESS: Yes.  
25

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09:41:09 1 BY MR. NORTH:

2 Q Does that look like that is the PowerPoint?

3 A Yes. Yes, that does.

4 Q Who prepared this PowerPoint?

09:41:17 5 A My regulatory correspondent on this file. And then we  
6 would have gotten the team from Bard that was going to be  
7 attending, and we would have all given input on this.

8 Q So did you have input into this -- making this PowerPoint  
9 presentation?

09:41:36 10 A Did I have input? Yes.

11 Q And was this PowerPoint then maintained as a part of the  
12 company's business files?

13 A Yes. I believe it's actually attached to the contact  
14 report or the meeting minutes.

09:41:51 15 Q And was this PowerPoint displayed, presented to the FDA?

16 A It was.

17 MR. NORTH: Your Honor, subject to later review  
18 between the parties, I would tender 5942.

19 MR. LOPEZ: No objection. I mean, objection, but no  
09:42:09 20 objection.

21 THE COURT: All right. Admitted subject to further  
22 conferring on hearsay within hearsay.

23 (Exhibit 5942 admitted.)

24 BY MR. NORTH:

09:42:16 25 Q Were copies of this presentation actually given to the

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09:42:22 1 FDA, to your knowledge?

2 A Yes. We usually e-mail the presentation itself to our  
3 contact there, and either they make copies for all attendees  
4 or they request that we do that.

09:42:45 5 Q As a part of this presentation, did the company share  
6 complication rates with the FDA?

7 A Yes, we did.

8 MR. NORTH: If we could turn to page 26, please.

9 Your Honor, I'd like to publish page 26.

09:43:10 10 MR. LOPEZ: That's fine, Your Honor.

11 THE COURT: You may.

12 BY MR. NORTH:

13 Q So at this time at this meeting in January of 2010, did  
14 the company notify -- or provide the FDA with detailed  
09:43:27 15 information regarding reports of fracture with the filters?

16 MR. LOPEZ: Your Honor, again -- I'm sorry about  
17 that -- again, he's leading. When he says "detailed," that's  
18 his -- him testifying, not the witness.

19 MR. NORTH: I'll rephrase, Your Honor.

09:43:41 20 THE COURT: Yeah, rephrase the question.

21 BY MR. NORTH:

22 Q And what sort of information did the company provide the  
23 FDA regarding the incidence of fractures?

24 A Historical information reported from field use of Bard IVC  
09:43:54 25 filters, including a rate, which normally isn't part of any

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09:44:00 1 submission.

2 Q At that time, did the company's data indicate that the G2  
3 fracture rate was lower than what had been reported for the  
4 Recovery filter?

09:44:14 5 A Yes.

6 Q By approximately how much?

7 A A fifth of what the original rate was. So 80 -- depending  
8 how you do the math. The Recovery rate would have been five  
9 times the fracture rate of the G2 rate, is what I'm trying to  
09:44:33 10 say.

11 MR. NORTH: If we could turn to Page 30, please.

12 THE COURT: Let's take it down and have plaintiff's  
13 counsel look at it first to see if there's a hearsay within  
14 hearsay concern.

09:44:57 15 MR. NORTH: Okay.

16 Could you show 30 on the screen.

17 MR. LOPEZ: No objection, Your Honor.

18 THE COURT: You may display it.

19 MR. NORTH: Thank you, Your Honor.

09:45:15 20 BY MR. NORTH:

21 Q Explain to us what this chart that was shown to the FDA as  
22 part of the PowerPoint depicts.

23 A So this, again, I believe is information derived from  
24 reported complications on field distributed product comparing  
09:45:37 25 the Recovery filter to the G2 to the G2X for the categories



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09:45:42 1 that are here, death, surgical intervention -- oh, sorry.

2 Summary of all of the filter fractures and this equality that  
3 occurred with them.

4 Q How many of the reports of filter fracture with regard to  
09:46:05 5 the G2 were asymptomatic patients?

6 A So the second line is surgical intervention -- I'm sorry.  
7 Patient asymptomatic would be the one, two, three, four, fifth  
8 line, and so 79 G2 filters were reported as asymptomatic.

9 Below that, as well, in cases where the filter was  
09:46:48 10 actually removed, there were additional 15 patients that were  
11 asymptomatic.

12 Q As of this time period, 2005 to 2009, had the company  
13 received any reports of a patient dying from a fracture?

14 A No.

09:47:09 15 Q At this point, as of -- through 2009, prior to the  
16 January 2010 meeting, how many reports had the company  
17 received of fracture of a G2 requiring surgical intervention?

18 A Four. Oh -- yeah, four. Um-hmm.

19 MR. NORTH: If we could go to page 34 -- I guess  
09:47:40 20 we'll take it off the screen first.

21 THE COURT: Yes, please.

22 MR. NORTH: Any objection to this?

23 MR. LOPEZ: I'm sorry. No. No.

24 THE COURT: All right. You may display it.

25

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09:48:08 1 BY MR. NORTH:

2 Q Did the company also present the FDA with information  
3 regarding migrations that had been reported?

4 A Yes.

09:48:27 5 MR. NORTH: Okay. We can take that down.

6 BY MR. NORTH:

7 Q You mentioned a moment ago, Mr. Van Vleet, a 2010 FDA  
8 safety communication. Was that communication specific to Bard  
9 in any way?

09:48:43 10 A No. We actually -- part of the reason for this meeting  
11 was to understand the genesis of that communication and how it  
12 arose, and Dr. Bram Zuckerman, who is the head of the Division  
13 of Cardiovascular Devices, told us, and then later actually  
14 reported in a news report that FDA had some concerns about  
09:49:04 15 these devices as a class, but it was not specific to any one  
16 company.

17 Q What was the general message in the FDA communication?

18 A Basically it was reminding --

19 THE COURT: Hold on just a minute.

09:49:22 20 MR. LOPEZ: Hearsay. He's asking him --

21 THE COURT: Sustained.

22 BY MR. NORTH:

23 Q Let me ask you this, Mr. Van Vleet: Did the FDA  
24 communication reference Bard filters?

09:49:38 25 MR. LOPEZ: Your Honor, again, if he wants to show

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09:49:39 1 the communication, he can, but I think him testifying what's  
2 in a document is hearsay.

3 THE COURT: Over- -- well, I'm going to sustain on  
4 hearsay grounds.

09:49:48 5 BY MR. NORTH:

6 Q Did the company provide customers with a notification of  
7 its own after the issuance of the FDA communication?

8 A Yes, we did.

9 MR. NORTH: If we could show 5923, please.

09:50:04 10 BY MR. NORTH:

11 Q What is this?

12 A This is a letter signed by me that discusses the FDA  
13 communication and that we sent to all of our customers that  
14 had used our product.

09:50:24 15 Q And was this created and distributed as a part of the  
16 regular business routine of the company?

17 A Yes, sir.

18 Q And when you say it was distributed to all of your  
19 customers, how would that go about?

09:50:35 20 A So we maintain a list of every device that is purchased by  
21 any customer, and so we would send a communication to anybody  
22 who had ever ordered a Bard filter.

23 Q And did you personally sign this letter?

24 A I did.

09:50:52 25 Q And were you involved in the creation of this letter?

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09:50:54 1 A Yes, I was.

2 MR. NORTH: Your Honor, at this time we would tender  
3 5923.

4 MR. LOPEZ: Subject to our agreement regarding  
09:51:00 5 hearsay.

6 THE COURT: All right. Admitted on that basis.

7 (Exhibit 5923 admitted.)

8 MR. LOPEZ: It should not be published, Your Honor.  
9 I'd ask it not be published.

09:51:10 10 MR. NORTH: I'm not going to.

11 BY MR. NORTH:

12 Q During your ten years working with Bard, were you involved  
13 with IVC filters the entire time?

14 A Yes.

09:51:28 15 Q At any time did the FDA ever suggest that Bard should  
16 recall the G2 filter?

17 MR. LOPEZ: Objection, Your Honor. Foundation. Also  
18 hearsay. 403 -- 402.

19 THE COURT: What's your response on hearsay?

09:51:48 20 MR. NORTH: It's notice to the company. It's not for  
21 the truth of the matter asserted. It's whether the company  
22 had notice of any --

23 MR. LOPEZ: It also lacks a lot of foundation,  
24 Your Honor. Calls for speculation.

09:52:01 25 THE COURT: Okay. I'm going to overrule the

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09:52:03 1 foundation and the relevancy objections.

2 I think I want to hear your thoughts, Mr. Lopez, on  
3 the hearsay point.

4 MR. LOPEZ: Well, Your Honor, he's asking -- do you  
09:52:16 5 want me to do it here?

6 THE COURT: Yeah, let's talk at sidebar.

7 Ladies and gentlemen, if you want to stand up, we'll  
8 make this as quick as we can.

9 (Bench conference as follows:)

09:52:40 10 MR. LOPEZ: When he asks questions like that,  
11 Your Honor, it assumes the FDA had any basis for making -- for  
12 issuing such a directive.

13 THE COURT: Well, but the objection was hearsay.

14 MR. LOPEZ: Right. It is hearsay because --

09:52:54 15 THE COURT: So my question is, if he says did the FDA  
16 at any time suggest to Bard that it should recall any of its  
17 filters.

18 MR. LOPEZ: Right. That assumes a lot --

19 THE COURT: The assumption isn't your objection. The  
09:53:15 20 objection is hearsay.

21 MR. LOPEZ: Well, I did say foundation too, so. In  
22 other words, in order to ask that question and get a fair  
23 answer that doesn't mislead the jury, there has to be a  
24 foundation that the FDA was actually looking at stuff that  
09:53:30 25 would allow them to evaluate whether or not it should be

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09:53:33 1 recalled.

2 THE COURT: I don't agree with that. And I  
3 understand the argument. But that is not a proper foundation  
4 objection. A foundation objection for this witness is whether  
09:53:40 5 he has a basis for knowing whether or not the FDA ever did  
6 that.

7 It's fair cross-examination for you to say -- to  
8 bring out that he doesn't know whether or not the FDA had  
9 enough information to make that decision intelligently. But  
09:53:53 10 the foundation is his knowledge of the communication --

11 MR. LOPEZ: Right.

12 THE COURT: -- and that's been laid, I think, by the  
13 fact that for ten years he was responsible for IVC filters and  
14 regulatory affairs.

09:54:03 15 MR. LOPEZ: True.

16 THE COURT: But coming back to the hearsay point,  
17 here's what I'm wrestling with: If he says no, the FDA never  
18 suggested a recall, then he's not recounting any communication  
19 from the FDA that would be hearsay. If he says yes, what he's  
09:54:19 20 saying is yes, the FDA suggested that there be a recall.

21 It doesn't seem to me that's offered for the truth of  
22 the matter asserted.

23 MR. LOPEZ: Well, here's the point, though. If the  
24 mere fact that the FDA doesn't do something is like a  
09:54:36 25 declaration by the FDA that there was no reason to do

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09:54:41 1 something, the fact that the FDA doesn't do something, that  
2 implication is that the FDA -- I mean, has all of this data,  
3 all of this information, is studying it every day, and he's  
4 being -- he asked the question -- that's why it's so unfair,  
09:54:55 5 because we can't ask the FDA to come in here. He's asking and  
6 he's trying to imply to the jury that the FDA did an  
7 investigation to determine that this thing should not be --

8 THE COURT: So your point is that the silence of the  
9 FDA on a recall is itself a declaration?

09:55:11 10 MR. LOPEZ: There's no doubt about that.

11 THE COURT: That's what your objection is?

12 MR. LOPEZ: Yes.

13 THE COURT: What's your response, Mr. North?

14 MR. NORTH: First of all, under Georgia law, I think  
09:55:27 15 the absence of a recall of a mass-produced product is relevant  
16 on the risk utility.

17 THE COURT: This isn't a relevancy objection.

18 MR. NORTH: On the hearsay, I don't -- I'm really  
19 struggling how that can be an assertion. It's just that  
09:55:44 20 whether they took a regulatory action or whether they didn't.

21 THE COURT: Respond to this point. I think part of  
22 what Mr. Lopez is saying is that his answering that question,  
23 though, is tantamount to his testifying that the FDA had no  
24 concerns about recall, and expressed the fact that it had no  
09:56:06 25 concerns about recall by never requesting, and that is, in

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09:56:10 1 effect, a declaration by the FDA.

2 And it seems to me that's why you want it in, you  
3 want to be able to argue to the jury that the FDA never  
4 requested a recall, never saw a reason to request a recall or  
09:56:23 5 they would have done so. It's a message from the FDA, it  
6 seems, you're trying to get into evidence.

7 MR. NORTH: Well, Your Honor, Mr. Lopez -- I think  
8 that's reading, first of all, too much into it. I understand  
9 the argument, but the FDA can take action or it may choose not  
09:56:43 10 to take action. It may imply a safe -- well, no public safety  
11 issue, or it may not have an implication.

12 If he wanted to make that point as to what the gist,  
13 the meaning of that was, he had regulatory experts designated  
14 in this case, he could have brought them if he wanted to  
09:57:06 15 question the legal -- or not the legal, but the practical  
16 impact of the FDA doing nothing.

17 The fact of the matter is they have never requested a  
18 recall. That's all Mr. Van Vleet is saying. I don't think  
19 that is an assertion, it's just establishing the fact that  
09:57:23 20 that regulatory action was never taken.

21 THE COURT: Let me ask this question: How much  
22 longer do you have with this witness?

23 MR. NORTH: About two or three, five minutes.

24 THE COURT: And your cross will be?

09:57:35 25 MR. LOPEZ: Longer. I'm hoping it's 20 if he



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09:57:38 1 cooperates with me. We'll see.

2 THE COURT: The reason I was asking was to see if we  
3 would be still going at the break, which is not for 30  
4 minutes.

09:57:45 5 What I'd like to do before I rule on this is look  
6 again at the case law on when silence is a declaration for  
7 purposes of the hearsay rule. I know there are cases that say  
8 it is. I just can't remember them well enough to make an  
9 informed decision on whether this is such an instance.

09:58:01 10 But why don't we do this: Go ahead and finish your  
11 questioning without bringing this subject up. Have  
12 Mr. Van Vleet remain until after the break.

13 MR. NORTH: Absolutely.

14 THE COURT: I'll look at the case law on the break.  
09:58:19 15 If I sustain the objection, we'll be done with him. If I  
16 overrule it, I'll allow you to call him back to put that  
17 question to him.

18 Is that a reasonable resolution?

19 MR. LOPEZ: Yes. Your Honor, may I ask, though, to  
09:58:32 20 also consider the 402, 403 issues here because there's an  
21 implication from that that the FDA actually sat down and  
22 evaluated whether or not a recall was necessary when he's  
23 asked that question. And that's -- I mean, that's the only  
24 reason why he's asking is everything's hunky-dory at FDA, and  
09:58:50 25 that is prejudicial, misleading.

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09:58:52 1 THE COURT: I will consider that argument.

2 Jeff, would you come here for a minute.

3 And, Jeff, for purposes of the break, where I'll have  
4 about five minutes, could you find a section in Weinstein's on  
09:59:13 5 hearsay that talks about when silence is a declaration for  
6 purposes of the hearsay rule. The argument Mr. Lopez has made  
7 is that the FDA's failure to recall or issue a request for  
8 recall is being introduced, in effect, as a declaration by the  
9 FDA that it had no concerns about recall. And I want to look  
09:59:36 10 again at the law on when silence is a declaration. I remember  
11 there's something in Weinstein's on that, I just can't  
12 remember the contours of it.

13 MR. KILMARK: I think we referenced it in one of our  
14 motions in limine as well.

09:59:50 15 THE COURT: Yeah, if you could find that over the  
16 break.

17 MR. NORTH: I want to raise one thing.

18 THE COURT: I don't want to prolong this at sidebar.

19 MR. NORTH: One thing. Even if that were to be  
09:59:58 20 hearsay, it seems to me I should be able to still ask did you  
21 ever receive word -- or some way -- because the reasonableness  
22 of their conduct. So the notice is not being offered for the  
23 truth of the matter asserted. We can address that later.

24 THE COURT: But if you ask him, did you, as the  
10:00:19 25 regulatory affairs vice president, ever receive any

## DIRECT EXAMINATION - JOHN VAN VLEET

10:00:23 1 information to cause you to think that the FDA was requesting  
2 a recall, and if he says no, it's exactly the same point, it  
3 seems to me. I understand it's phrased in terms of notice,  
4 but the relevancy, it seems to me, is still that the FDA never  
10:00:37 5 requested a recall.

6 MR. LOPEZ: Don't go away.

7 THE COURT: I don't want to prolong this.

8 MR. LOPEZ: I know, but the warning letter, I'm  
9 telling you this, he's opened the door wide open.

10:00:47 10 THE COURT: We'll talk about that later.

11 MR. LOPEZ: I want it all to come in.

12 THE COURT: We'll talk about that later.

13 (Bench conference concludes.)

14 THE COURT: All right. Thank you, ladies and  
10:00:52 15 gentlemen.

16 BY MR. NORTH:

17 Q Mr. Van Vleet, over the course of your decade with Bard,  
18 did you become familiar with Bard's processes and procedures  
19 regarding corrective actions?

10:01:18 20 A Yes.

21 Q What sorts of procedures did the company have?

22 A So those are mostly handled through the quality  
23 organization, but basically all information about the  
24 performance of a product or any input that we would get from  
10:01:34 25 customers is evaluated, and it's fed back into the corrective

## CROSS-EXAMINATION - JOHN VAN VLEET

1 action procedure process, and it drives certain actions or  
2 certain activities depending on what the feedback is. It's  
3 the way you learn about the performance of the devices and how  
4 medical device companies learn how to improve products.

10:01:59 5 Q If Bard internally determines that a product is not safe  
6 for some reason or that the risks outweigh the benefits, what  
7 types of actions can the company take? Or does it take?

8 A It can stop distributing it, it can communicate with the  
9 customer, or it can actually recall it from the field.

10:02:17 10 Q Over the course of your ten years at Bard, to your  
11 knowledge, did the company ever internally determine that the  
12 G2 filter was unsafe?

13 A No.

14 Q Has Bard ever determined that the G2 should be recalled  
10:02:31 15 based on internal company policies?

16 A No.

17 MR. NORTH: Thank you, sir. That's all I have.

18 THE COURT: All right. Cross-examination?

## C R O S S - E X A M I N A T I O N

10:02:39 20 BY MR. LOPEZ:

21 Q Good morning, Mr. Van Vleet.

22 A Good morning.

23 Q Let me ask you, I know you were -- you got involved with  
24 the G2 while the EVEREST study, I think it had already  
10:03:16 25 concluded; correct?

## CROSS-EXAMINATION - JOHN VAN VLEET

10:03:17 1 A It was -- yes. Essentially it was done. It was just data  
2 analysis at that point.

3 Q And during the entire time that you were interacting with  
4 FDA, was there ever a new regulation that came down or an act  
10:03:32 5 of Congress that relieved Bard of their obligation to maintain  
6 substantial equivalence to a predicate device?

7 A For any product or --

8 Q No, for this product, the G2.

9 A Oh, this product. Okay. Not to my knowledge.

10:03:48 10 Q And you know that the Simon Nitinol filter was the  
11 predicate for the Recovery filter; right?

12 A I believe it was. That predates me.

13 Q And you also -- you also know that even though the  
14 Recovery filter was the predicate for the G2, that other  
10:04:04 15 people have testified in this courtroom, including an expert,  
16 that says the G2 was still required to maintain the same  
17 safety and effectiveness profile as the Simon Nitinol filter.

18 Did you know that?

19 A I haven't been privy to any of the testimony here.

10:04:20 20 Q That makes sense to you, doesn't it?

21 A It sounds logical.

22 Q Okay. Now, I noticed -- I don't want to put the slides up  
23 again for time purposes, but the presentations that were made  
24 to FDA, there were no comparisons of the G2 to the  
10:04:34 25 Simon Nitinol filter in any of those charts. True?

## CROSS-EXAMINATION - JOHN VAN VLEET

10:04:38 1 A That is true, I believe.

2 Q I noticed you had -- one of the reports was the summary of  
3 the findings in the EVEREST trial, and I want to know, is  
4 there a report that Bard prepared, that you prepared, that you  
10:05:01 5 asked FDA if you can make this -- I'm sorry -- where you  
6 determined that you ought to make this presentation to the  
7 Society of Interventional Radiologists, to the American  
8 College of Radiology, or to your customers at large about the  
9 findings in the EVEREST study?

10:05:19 10 A I'm sorry, can you repeat the question.

11 Q Yeah. I want to know whether or not you ever proposed  
12 instead of just giving a report to the FDA, who does not  
13 proscribe your device; right?

14 A Correct.

10:05:30 15 Q They don't test it, they didn't test this device. True?

16 A FDA has a testing lab. I don't know if they tested  
17 this --

18 Q They didn't test this device.

19 A Okay.

10:05:39 20 Q Do you know if they tested this device?

21 A I don't know if they did and I don't know if they didn't.

22 Q Did they design it?

23 A No.

24 Q Did they market it?

10:05:45 25 A No.

CROSS-EXAMINATION - JOHN VAN VLEET

10:05:46 1 Q Did they make any money selling it?

2 A I certainly don't think so.

3 Q Did they have any direct contact with the people that Bard  
4 was selling this device to?

10:05:57 5 A Not in an orchestrated form, but yes, they're involved in  
6 their societies.

7 Q Were they making day-to-day decisions on whether or not  
8 the G2 device was as safe and effective as it was being  
9 represented by the company to be? Anyone at FDA doing that?

10:06:15 10 A The information that's received for complaints for devices  
11 is evaluated by certain branches at FDA, that presumably  
12 that's part of their charter. That's a kind of quality  
13 question. From a regulatory perspective, I'm not aware of it.

14 MR. LOPEZ: Could I have Exhibit 5298, please.

10:06:37 15 BY MR. LOPEZ:

16 Q Now, sir, you testified there was one fracture in the  
17 EVEREST study. True?

18 A I believe that.

19 Q And that is what was reported in the Binkert article that  
10:06:45 20 was published in 2009; correct?

21 A Correct.

22 MR. LOPEZ: Could you put up 5290 for Mr. Van Vleet.  
23 Final report.

24 Let me give you the Bates number, Greg. It ends in  
10:07:24 25 3967. The first page actually ends in 3967.

CROSS-EXAMINATION - JOHN VAN VLEET

10:07:55 1 We'll come back to that, Your Honor, after the break.

2 I apparently got a wrong trial exhibit number.

3 BY MR. LOPEZ:

4 Q Okay. Mr. Van Vleet, who is Dr. John Lehmann?

10:08:08 5 A I believe he was a consultant for Dr. David Ciavarella,  
6 who is the clinical officer.

7 Q You don't remember Dr. Lehmann?

8 A I'm not sure he and I actually ever met face-to-face.

9 Q And who is Dennis Salzman?

10:08:25 10 A He was the director of regulatory affairs.

11 Q Is he a medical doctor?

12 A No.

13 Q Did he have any medical background?

14 A Yeah, he has a Ph.D. in cardiovascular physiology, so --.

10:08:37 15 And he studied under Dr. Berman in Tucson.

16 Q And did Mr. Salzman ever express any concern to you about  
17 the revisions that Dr. Lehmann was suggesting -- suggesting he  
18 made in the final EVEREST report?

19 A I don't know if Dr. Salzman did. I can't specifically  
10:08:59 20 recall.

21 MR. LOPEZ: Could we call up your exhibit -- I'm  
22 sorry, your deposition that was taken in this case. Page 148,  
23 line 16 through 22, please.

24 MR. WOODY: Which page?

10:09:29 25 MR. LOPEZ: December 29, 2016.



CROSS-EXAMINATION - JOHN VAN VLEET

10:09:36 1 MR. WOODY: Which page do you want?

2 MR. LOPEZ: Page 148, line 16 through 22.

3 BY MR. LOPEZ:

4 Q Do you see that, sir?

10:09:53 5 A I do.

6 Q Remember your deposition being taken?

7 A I do.

8 Q And you were asked this question: In the e-mail exchange,

9 the first e-mail is the e-mail from Dennis Salzman to you and

10:10:03 10 John Reviere, among the other members of the team. He's

11 commenting on the revisions that Dr. Lehmann made in revision

12 H of the final study report; correct?

13 And you said, "correct"; right?

14 A Yes.

10:10:14 15 Q Does that refresh your recollection that Dr. Salzman was

16 concerned about some of these revisions that were being made

17 by Dr. John Lehmann?

18 A Sure. My response was looking at the e-mails, so if I had

19 it in front of me, it probably would be more helpful.

10:10:37 20 Q Who is Vanessa Dell?

21 A I'm not sure.

22 Q Do you know who Vanessa Dell is?

23 A I'm not sure.

24 Q Do you know what her involvement was with the final

10:10:47 25 report?

CROSS-EXAMINATION - JOHN VAN VLEET

10:10:49 1 A I don't.

2 Q And was one of the things that Dr. Lehmann did not want to  
3 include in the final report was any reference to the SIR  
4 guidelines, a 2003 article written by Dr. Grassi and others?

10:11:05 5 A I'd have to see the interaction to refresh my memory.

6 MR. LOPEZ: Could you please call up page 235 of  
7 Mr. Van Vleet's deposition, lines 11 through 17.

8 BY MR. LOPEZ:

9 Q "Do you recall having a disagreement with him" -- and I'll  
10 represent to you that that's Dr. Lehmann -- "about whether or  
11 not the report should reference the SIR guidelines. True?"

12 "Answer: Yes; correct.

13 "Dr. Lehmann didn't want to include that and you did.  
14 True?"

10:11:40 15 "Yes. I don't think he was aware of them."

16 Does that refresh your recollection about your  
17 objection to a physician who was helping to prepare this  
18 report to the inclusion of SIR guidelines in the final report?

19 A Yeah. Again, I'm sure I was --

10:11:58 20 Q You were aware of that; right? You were aware that  
21 Dr. Lehmann did, in fact, object to putting the SIR guidelines  
22 in the final report?

23 A I'm sure that when I reviewed the documentation, I would  
24 have seen that.

10:12:08 25 Q And is that because those guidelines are not meant to

## CROSS-EXAMINATION - JOHN VAN VLEET

10:12:09 1 guide -- they're only meant to guide physicians, and they're  
2 not meant for manufacturers' use to do comparisons among their  
3 own devices?

4 A I don't know why he objected.

10:12:19 5 MR. LOPEZ: Page 274, lines 12 through 16, please, of  
6 the same deposition.

7 BY MR. LOPEZ:

8 Q "Based on your understanding of the guidelines they were  
9 not intended for manufacturers. True?"

10:12:34 10 "Answer: I don't think they were intended for  
11 anybody but perhaps the clinician."

12 Was that your answer, sir, at your deposition?

13 A It was.

14 Q So let's go back and let's discuss the EVEREST final  
10:12:45 15 report again.

16 There was discussions among your colleagues at Bard  
17 to change the definition of "migration" in the EVEREST final  
18 report, and you were part of that discussion; right?

19 A I'm not sure if I was or not. I'd have to go back and  
10:13:05 20 look.

21 MR. LOPEZ: Page 238, lines 14 through 24, please.

22 BY MR. LOPEZ:

23 Q "Do you know who at Bard had made the suggestion that  
24 Dr. Lehmann is responding to regarding the change of the  
10:13:25 25 definition of migration?"

## CROSS-EXAMINATION - JOHN VAN VLEET

10:13:26 1 "Answer: I don't know in particular on that. I know  
2 there was discussion of the SIR" --

3 MR. LOPEZ: Your Honor, could I publish this, as  
4 well, to the jury?

10:13:33 5 THE COURT: No. This is not an exhibit.

6 MR. LOPEZ: Okay.

7 BY MR. LOPEZ:

8 Q "I don't know in particular on that. I know there was  
9 discussion of the SIR guideline of 2 centimeters for a  
10:13:42 10 definition of migration and where that should be, whether it  
11 is 2 and under or under 2."

12 "Question: Do you recall if you made that  
13 suggestion?

14 "I certainly was part of a discussion."

10:13:54 15 Does that help refresh your recollection?

16 A Yes, I do. I do recall this.

17 Q Had you and your colleagues been successful in changing  
18 the definition, it would have eliminated three patients from  
19 being counted as a migration in that study. True?

10:14:10 20 A We didn't change the definition of migration.

21 Q You were trying to. My question to you is: Had you been  
22 successful in talking Dr. Lehmann into changing the migration  
23 to suit whoever it was, you and your colleagues, it would have  
24 actually lowered the rate of migration in the study. True?

10:14:28 25 A That wasn't the reason for the discussion of changing the

## CROSS-EXAMINATION - JOHN VAN VLEET

10:14:30 1 definition.

2 MR. LOPEZ: Page 239, line 8 through 14, please.

3 BY MR. LOPEZ:

4 Q "The discussion continues that changing the -- the

10:14:44 5 definition of migration in the way Bard is suggesting would

6 eliminate three patients from the migration complication pool;

7 correct?"

8 "Answer: It's -- that's what he said. If

9 implemented, it would result in the post hoc exclusion of

10:14:59 10 three subjects."

11 Does that refresh your recollection about that issue?

12 A I remember him reading that from an e-mail that

13 Dr. Lehmann wrote; correct.

14 Q How many fractures, again, were reported in the EVEREST  
10:15:13 15 study?

16 A One.

17 MR. LOPEZ: Could I now see Trial Exhibit 5290.

18 Can you go to Bates 40 -- wait a minute. Where am I?

19 Bates 4028, please.

10:15:53 20 Go to -- like at the very top, there's pages from the  
21 actual report, and it says page 364 on the upper right-hand  
22 corner.

23 It's probably about -- can I see the next page so I  
24 can see what -- all I have is a blank page.

10:16:25 25 Search table 15.

CROSS-EXAMINATION - JOHN VAN VLEET

1 Well, you know what, Your Honor, I'm just going to  
2 show it on the Elmo so we don't struggle through this exhibit.

3 BY MR. LOPEZ:

4 Q Sir, do you see what I'm looking at here, table 15?

5 A Yeah, I do.

6 Q Okay. In fact, this patient ID number, 04001 --

7 THE COURT: Mr. Lopez, excuse me. This exhibit is  
8 not in evidence.

9 MR. LOPEZ: It is, Your Honor.

10 THE COURT: 5290 has not been admitted.

11 MR. LOPEZ: I'd like to offer it at this time,  
12 Your Honor.

13 THE COURT: Any objection to 5290?

14 MR. NORTH: I'm sorry, what's the cover page?

15 THE COURT: What is the exhibit, Mr. Lopez?

16 MR. LOPEZ: 5290.

17 THE COURT: No. What is the document?

18 MR. LOPEZ: It's the final -- the Bard Recovery G2  
19 Final Study, EVEREST Final Study Report.

20 MR. NORTH: No objection, Your Honor.

21 THE COURT: All right. 5290 is admitted.

22 (Exhibit 5290 admitted.)

23 BY MR. LOPEZ:

24 Q Do you recognize this, Mr. Van Vleet?

25 A Yes. It looks like it's a summary narrative for this

## CROSS-EXAMINATION - JOHN VAN VLEET

10:17:53 1 patient's complications.

2 Q And, in fact, what was reported to you was that there was  
3 one fractured filter arm and one fractured filter leg.

4 MR. LOPEZ: Could we publish this to the jury,  
10:18:06 5 Your Honor?

6 THE COURT: Yes.

7 BY MR. LOPEZ:

8 Q Do you see where I am? Right here. It's highlighted.

9 "One fractured filter arm and one fractured leg were  
10:18:20 10 noted in the extravascular space. Retrieval was unsuccessful  
11 despite extensive effort because the apex of the filter  
12 appeared to be embedded in the IVC wall and could not be  
13 engaged by the Recovery cone."

14 Do you see that?

10:18:36 15 A Yes.

16 Q Was this case and the details of this case ever shared  
17 with any of the physicians or hospitals that were purchasing  
18 the G2 filter?

19 A This would have been shared with every participating  
10:18:50 20 investigator in the trial, as well as FDA.

21 Q No, I'm asking whether or not doctors who are actually  
22 buying a G2 and making this risk/benefit decisions were  
23 advised of this particular case that happened in a controlled  
24 clinical study?

10:19:05 25 A Yeah, I don't know if that was included in the Binkert

## CROSS-EXAMINATION - JOHN VAN VLEET

10:19:07 1 paper, so -- that would have been one way it could have been.

2 Q How about in 2006?

3 A I wasn't employed by Bard at that time.

4 Q Well, in 2007 doctors wouldn't have known about this  
10:19:19 5 unless Bard had told them; right?

6 A Presumably, yeah.

7 Q Now, Dr. Lehmann -- let's go back to Dr. Lehmann.

8 He also advised that the conclusion section of the  
9 final report as it was being proposed by you and your  
10:19:47 10 colleagues at Bard did not support a regulatory statement that  
11 he felt needed to be modified. Do you remember that?

12 A I'd have to see it to -- there was a series of e-mails  
13 from him that I was reviewing, I think, when I was giving this  
14 deposition.

10:20:06 15 Q Let's see if this helps refresh your recollection.

16 "And specifically he stated that a statement that the  
17 EVEREST trial demonstrated substantial equivalence to similar  
18 devices was obviously not a true statement."

19 He said that to you and your colleagues at Bard who  
10:20:21 20 were following this report. Do you recall that?

21 A I'd have to see it to understand the context.

22 MR. LOPEZ: Trial Exhibit 2292, please.

23 2252. My apologies. 2252.

24 BY MR. LOPEZ:

10:20:46 25 Q Do you recognize this, sir?



CROSS-EXAMINATION - JOHN VAN VLEET

10:21:15 1 A Yes.

2 Q And could you -- are you on this e-mail?

3 A I am on the one at the bottom of the page.

4 MR. LOPEZ: Could we go to the next page, Greg.

10:21:34 5 BY MR. LOPEZ:

6 Q Okay. This is -- this shows that Dr. John Lehmann is  
7 involved in this study and you and he are communicating back  
8 and forth; correct?

9 A Correct.

10:21:50 10 MR. LOPEZ: Greg, can I have Bates number 348285.

11 MR. WOODY: Not this document?

12 MR. LOPEZ: No, a different document.

13 MR. WOODY: Which document?

14 MR. LOPEZ: I'm sorry.

10:22:33 15 Okay. Did you find it?

16 MR. WOODY: Is it 2252?

17 MR. LOPEZ: It is 2252.

18 Okay. Let's go to Bates 8286, please.

19 Okay. Let's go to -- there you go.

10:23:52 20 No, that's a different number.

21 Your Honor, I'm sorry. The Bates numbers I was given  
22 for the exhibit is a different Bates number than what we're  
23 showing here.

24 So I need 8286 is the Bates number I need, of Exhibit  
10:24:14 25 2252. Of course, it's a different Bates here.

CROSS-EXAMINATION - JOHN VAN VLEET

10:24:20 1 BY MR. LOPEZ:

2 Q Sir, let me show you an e-mail here, and you recall that  
3 you had communications with Dr. John Lehmann; correct?

4 A Correct.

10:25:24 5 Q And I asked you about whether Dr. Lehmann had recommended  
6 that certain language not be included in the final report.

7 Do you see where I am?

8 THE COURT: Mr. Lopez, this document is not in  
9 evidence.

10:25:42 10 MR. LOPEZ: Your Honor, I'd like to move it into  
11 evidence at this time. It's 2252.

12 MR. NORTH: No objection, Your Honor.

13 THE COURT: Admitted.

14 (Exhibit 2252 admitted.)

10:25:49 15 BY MR. LOPEZ:

16 Q See where I am, Section 10?

17 A Yes.

18 Q Okay. On reading -- on rereading the document, this is  
19 Dr. Lehmann speaking to you; correct? Or this is a report to  
10:26:02 20 you about Dr. Lehmann.

21 MR. LOPEZ: I'd like to publish this to the jury,  
22 Your Honor.

23 THE COURT: You may.

24 BY MR. LOPEZ:

10:26:11 25 Q Do you see where I am? Where it says "Section 10,

## CROSS-EXAMINATION - JOHN VAN VLEET

10:26:15 1 discussion and conclusion." I have a checkmark right by it.

2 Do you see it?

3 A Yes.

4 Q Okay.

10:26:23 5 "On rereading the document, I realize that we have an  
6 unsupported regulatory statement that needs modification  
7 relating to the EVEREST trial demonstrating substantial  
8 equivalence to similar devices which it obviously didn't do.  
9 So I've deleted the sentence."

10:26:41 10 Do you see that, sir?

11 A I do see that.

12 Q That is Dr. Lehmann, a physician who -- by the way, do you  
13 know he was a consultant to Bard with the Recovery filter as  
14 well?

10:26:52 15 A He was.

16 Q In fact, he did a statistical analysis that is in an HHE  
17 and a --

18 MR. NORTH: Objection, Your Honor. Privilege.

19 THE COURT: Sustained.

10:27:02 20 MR. LOPEZ: It's in -- okay. We'll talk about it,  
21 Your Honor.

22 BY MR. LOPEZ:

23 Q But in any event, Dr. Lehmann is telling you to not put  
24 certain language in the report because he believes it not to  
10:27:14 25 be true.

## CROSS-EXAMINATION - JOHN VAN VLEET

10:27:15 1 A So Dr.- -- that would be his opinion; correct.

2 Q And, in fact, you ignored that, didn't you? You ignored  
3 that?

4 A I really don't know why he said that. I have no idea.

10:27:25 5 All of the information we collected was submitted to the FDA.

6 They make the ultimate determination of substantial --

7 Q Well, but you submit the document. FDA doesn't write this  
8 report; correct?

9 A All of the data are submitted to FDA, and they make the  
10:27:40 10 determination, so --

11 Q I'm going to show you page 77 of Trial Exhibit 5290, and  
12 you'll see here at the bottom, that advice by Dr. Lehmann was  
13 ignored. True?

14 It reads: The overall study results constitute valid  
10:28:03 15 scientific evidence regarding the overall performance of Bard  
16 Recovery G2 filter system as an IVC filter and serves as a  
17 valid basis for comparison in determining that the Recovery G2  
18 filter is substantially equivalent to similarly marketed  
19 devices.

10:28:22 20 Right?

21 A I believe that statement to be true.

22 Q And got your way on that one.

23 A I'm not sure what you mean.

24 Q Well, didn't you ultimately decide to fire Dr. Lehmann and  
10:28:34 25 get him off this report?

CROSS-EXAMINATION - JOHN VAN VLEET

10:28:35 1 A Dr. Lehmann was not an employee of mine.

2 Q You decided -- someone decided at Bard that Dr. Lehmann  
3 ought to be taken off this report.

4 A Dr. Lehmann reported to Dr. Ciavarella, and I'm not sure  
10:28:48 5 what their conversations were.

6 MR. LOPEZ: Page 150, lines 1 through 5 of your  
7 deposition, please.

8 BY MR. LOPEZ:

9 Q "And then, apparently, you had decided that -- that John  
10:29:12 10 Lehmann was no longer to be used by the company."

11 "Answer: I preferred not to work with Dr. Lehmann;  
12 correct."

13 A That is correct.

14 Q I think I heard you say that there was only 61 patients  
10:29:30 15 that -- where the device was actually removed in the EVEREST  
16 study.

17 A That sounds close, yeah. I don't know that I said that  
18 today, but I'd have to look at the table.

19 THE COURT: All right. We're at the 10:30 mark.  
10:29:44 20 We're going to break, ladies and gentlemen, until 10:45.

21 We will excuse the jury at this time.

22 (Recess was taken from 10:30 to 10:45. Proceedings  
23 resumed in open court with the jury present.)

24 THE COURT: Mr. Lopez, Mr. North, would you approach  
10:45:56 25 a minute.

## CROSS-EXAMINATION - JOHN VAN VLEET

(Bench conference as follows:)

THE COURT: All right. Counsel, I had an opportunity over the break to look at this silence is hearsay issue. Two sources I looked at. One is my order, which is a document at Docket 10258. It is my March 1st order on motions in limine. There, I noted that absence of a statement generally is not hearsay. That's the general rule. But case law has recognized that a statement -- pardon me -- silence can be a statement for purposes of the hearsay rule where the person, the declarant, intended the silence as an assertion.

And there's a District of Idaho case cited which says "Rule 801 explicitly requires that the declarant must actually intend his statement, even if it consists of silence, as an assertion."

Weinstein's Section 801.10 makes the same point.

There's an even more relevant discussion in McCormick on Evidence, Section 250, which talks about silence is hearsay, and it gives a specific example of cases where evidence of absence of complaints from customers is offered to disprove claimed defects of goods or food from other persons or from other persons who would have been affected. So silence in a product defect case to suggest there wasn't a defect.

And McCormick says the evidence is not hearsay under the definition of hearsay because it is not intended as an

## CROSS-EXAMINATION - JOHN VAN VLEET

10:47:52 1 assertion.

2 Here's my conclusion.

3 I have no basis to conclude that the FDA's failure to  
4 request a recall was intended by the FDA as an assertion, and  
10:48:05 5 therefore it is not covered by the hearsay rule. And I'm  
6 going to overrule the objection.

7 So I'm going to allow you to ask the question on  
8 redirect. If you want to cross on that point, I'll allow you  
9 to do a recross, which I normally don't allow, but if you  
10:48:23 10 decide to do it after you've heard that answer.

11 That's my ruling.

12 (Bench conference concludes.)

13 THE COURT: Thank you, ladies and gentlemen.

14 MR. LOPEZ: May I proceed, Your Honor?

10:48:44 15 THE COURT: Yes.

16 MR. LOPEZ: Could we pull up Exhibit 5602. It was  
17 used by defense counsel.

18 Could we just show it to the witness.

19 The subject -- just that whole top section, Greg,  
10:49:06 20 please.

21 BY MR. LOPEZ:

22 Q Sir, you recall that you were asked questions about this,  
23 this is an FDA meeting?

24 A Yes.

10:49:17 25 Q And the subject of the meeting was about the Recovery, the

CROSS-EXAMINATION - JOHN VAN VLEET

10:49:22 1 G2, the G2X fractures, and Nicholson publication, slash,  
2 presentation. True?

3 A True.

4 Q Okay. That wasn't clear during your direct examination  
10:49:33 5 with Mr. North.

6 So you were there to discuss with the FDA issues  
7 regarding Recovery, G2, G2X fractures, and a publication by a  
8 Dr. Nicholson?

9 A Yes.

10:49:50 10 MR. LOPEZ: Exhibit 3814, please.

11 BY MR. LOPEZ:

12 Q Is this the Nicholson study that was the subject of that  
13 meeting?

14 A I'm trying to see what the journal's name is.

10:50:07 15 Q It's in the American --

16 A Yes, I believe so.

17 Q -- Medical Association journal.

18 A Yes.

19 Q This was published in November of 2010?

10:50:15 20 A Yes.

21 Q And the meeting you had with FDA was when?

22 A January of 2010, I believe.

23 Q So your company and the FDA already know about the  
24 findings of the Nicholson study before it was published?

10:50:33 25 A We were made aware of it because he presented on a



## CROSS-EXAMINATION - JOHN VAN VLEET

1 recorded conference that was available online and we were able  
2 to go through. And I can't recall if that also had the  
3 slides, but we were able to derive the numbers that he was  
4 asserting.

5 Q And this was published in the Archives of Internal  
6 Medicine?

7 A Yes.

8 Q And you recognize that as an authoritative journal?

9 A I don't work in internal medicine, and I really don't know  
10 that much about the journal, so --

11 Q But you're aware at the time of this meeting of the  
12 findings in the Nicholson study. True?

13 A Yes. Probably not as many as are in here, but to the  
14 general gist of it.

15 Q And that study was regarding the prevalence of fracture  
16 and fragment embolization.

17 What is embolization?

18 A It means when something goes through the bloodstream to a  
19 different location to where it was intended.

20 Q Like, for example, a fragment of a G2 filter that could go  
21 into a heart or lung, liver, or other locations. True?

22 A Correct.

23 Q "Bard retrievable vena cava filters and clinical  
24 implications including cardiac perforation and tamponade."

25 Is that what this study was about?

CROSS-EXAMINATION - JOHN VAN VLEET

10:51:47 1 A That's the title of the article; correct.

2 Q But this article is not about any other IVC filter but the  
3 Bard G2 filter --

4 A Correct.

10:51:56 5 Q -- and Recovery filter; correct?

6 A Yes.

7 MR. LOPEZ: Okay. Could we look at the results  
8 section, Greg, and show that.

9 MR. NORTH: Your Honor, I object. This is not in  
10:52:06 10 evidence.

11 MR. LOPEZ: Your Honor, I'll offer it into evidence,  
12 it is a medical article. I'd like to offer it at this time.  
13 It's the article that they were talking about at the meeting.

14 THE COURT: I understand that.

10:52:17 15 Any objection to its admission?

16 MR. NORTH: I would object, Your Honor, because I  
17 think under that exception it has to go through an expert.

18 THE COURT: Well, you're talking about 803(18)?

19 MR. NORTH: Yes.

10:52:29 20 THE COURT: That foundation has not been laid because  
21 he can't say it's a reliable journal. He testified --

22 What's the basis for this --

23 MR. LOPEZ: The basis is this is the subject matter  
24 of the meeting he went to with the FDA that was brought up  
10:52:40 25 during the --

## CROSS-EXAMINATION - JOHN VAN VLEET

10:52:41 1 THE COURT: It's still hearsay. What is the hearsay  
2 exception you're relying upon?

3 MR. LOPEZ: His notice and their frame of mind as --  
4 when they were at the meeting, and the discussions they had at  
10:52:49 5 FDA.

6 THE COURT: Your response?

7 MR. LOPEZ: Their -- I'm sorry.

8 THE COURT: Your response, Mr. North?

9 MR. NORTH: I think he did ask him about his  
10 awareness of it, but to read from it when it's not in  
11 evidence, I don't think so.

12 THE COURT: All right. I think you can ask him  
13 questions --

14 MR. LOPEZ: That's fair.

10:53:05 15 THE COURT: -- but shouldn't be reading from the  
16 article.

17 BY MR. LOPEZ:

18 Q Sir, when you were at the meeting, you had the data from  
19 the Nicholson study. True?

10:53:12 20 A I believe we had some of the data; correct.

21 Q And does the results section we just had blown up -- I'll  
22 let you look at it again -- help refresh your recollection of  
23 what some of those issues were?

24 A Yes.

10:53:23 25 Q And does this -- what you see accurately reflect what your

## CROSS-EXAMINATION - JOHN VAN VLEET

10:53:28 1 understanding was about the Nicholson -- what Dr. Nicholson  
2 found in his study?

3 A This is what he put in the abstract for the publication;  
4 correct.

10:53:40 5 Q And that -- so you're -- this helps refresh your  
6 recollection?

7 A It helps me refresh my memory about the issue in general.

8 Q And so was there, in fact, 80 patients that were part of  
9 the study?

10:53:59 10 A This is what he is asserting in this paper.

11 Q Right. And that 13 of those 80 patients had at least one  
12 fractured strut?

13 A This is what he's asserting in this paper; correct.

14 Q And that one strut in seven of the 28 Bard Recovery  
10:54:14 15 filters fractured and embolized --

16 MR. NORTH: Objection, Your Honor. He's just  
17 reciting hearsay.

18 THE COURT: You need to call on his memory, not the  
19 document.

10:54:24 20 MR. LOPEZ: Well, Your Honor, he said all of this  
21 refreshes his recollection.

22 THE COURT: Now he needs to set it aside and testify  
23 from his recollection.

24 BY MR. LOPEZ:

10:54:31 25 Q All right. So you can refer to this to refresh your

## CROSS-EXAMINATION - JOHN VAN VLEET

10:54:34 1 recollection.

2 THE COURT: No, he can't. His memory's been  
3 refreshed. You need to take the document down and have him  
4 testify from his memory.

10:54:42 5 MR. LOPEZ: May I see it, Greg.

6 BY MR. LOPEZ:

7 Q What was the fracture rate of the Bard Recovery in this  
8 study of 80 patients?

9 A I can't recall.

10:55:05 10 Q If you look at the document there, will that help refresh  
11 your recollection?

12 THE COURT: No, he's asking you, sir, not to read  
13 what's in the document. Look at it. If it refreshes your  
14 recollection of what Dr. Nicholson said, you can tell him, and  
10:55:16 15 he can ask you questions about your --

16 THE WITNESS: I don't remember the particulars. The  
17 reason for a meeting with FDA is because we hadn't been able  
18 to get any information on these reported complications from  
19 Dr. Nicholson.

10:55:26 20 BY MR. LOPEZ:

21 Q All right. But in any event, though, you were aware that  
22 Dr. Nicholson had found some alarming details about patients  
23 in a population he looked at that relate to G2 and Recovery  
24 filter fractures. True?

10:55:41 25 A Dr. Nicholson had made some alarming allegations, yes.

CROSS-EXAMINATION - JOHN VAN VLEET

10:55:45 1 Q And the embolization of some of those fractures to distant  
2 parts of people's bodies; right?

3 A Those were part of the allegations that he was making.

4 Q And it was shortly after the FDA's awareness of that that  
10:55:59 5 the FDA and you got together to discuss the G2 and Recovery  
6 filter?

7 A Yes.

8 Q Do you know whether or not Bard took any action against  
9 Dr. Nicholson? Like, did they threaten him in any way?

10:56:14 10 A I do know that we made 13 attempts to contact him to  
11 collect information to report to the FDA.

12 Q Right.

13 A Unsuccessfully.

14 Q Did he actually get letters from lawyers that were  
10:56:24 15 threatening letters to him?

16 A No.

17 Q You're not aware of a letter that was sent to --

18 A No.

19 Q -- Dr. Nicholson where he was threatened?

10:56:38 20 A No. That would not be in my area of responsibility.

21 MR. LOPEZ: That's all I have, Your Honor.

22 Oh, no. One more item. Exhibit 709. Last item.

23 BY MR. LOPEZ:

24 Q Do you recognize that document?

10:56:52 25 A Yes.

CROSS-EXAMINATION - JOHN VAN VLEET

10:56:53 1 Q I think you were the primary author of it; correct?

2 A I definitely approved it, for sure.

3 Q And could you go to page 6 of the document.

4 And this involves the Simon Nitinol filter; correct?

10:57:08 5 A So I think this is a draft, because the date on the front  
6 of that's not the right date. But in any event --

7 Q If you look at the bottom there --

8 MR. LOPEZ: I'd like to offer 709 into evidence at  
9 this time, Your Honor.

10:57:30 10 MR. NORTH: No objection, Your Honor.

11 THE COURT: Admitted.

12 (Exhibit 709admitted.)

13 BY MR. LOPEZ:

14 Q Sir, 709 deals with the Simon Nitinol filter; correct?

10:57:38 15 A Yes.

16 Q And you wrote --

17 MR. LOPEZ: And let's go down to the bottom  
18 paragraph, Greg, again --

19 May I publish this to the jury, please?

10:57:49 20 THE COURT: You may.

21 BY MR. LOPEZ:

22 Q See where it says again, "The first SNF 510(k)" --

23 A Um-hmm.

24 Q -- "was cleared on April 20th, 1990, and has been on the  
10:58:02 25 U.S. market for over 24 years as a permanent inferior vena

## CROSS-EXAMINATION - JOHN VAN VLEET

10:58:08 1 cava filter option."

2 Correct?

3 A Correct.

4 Q You wrote that.

10:58:12 5 "And then throughout its over two decades of clinical  
6 use, no evidence has been found to support a link between SNF  
7 permanent filter implantation and the serious health  
8 consequences that have been an expressed concern from FDA  
9 regarding removable IVC filters."

10:58:33 10 That's based on research did you; correct?

11 A Correct.

12 Q "Additionally, the use of the SNF is steadily declining  
13 year after year."

14 Correct?

10:58:45 15 A Yes.

16 Q But you had looked at your company's internal data and you  
17 reviewed the medical literature, and after doing so you  
18 learned that the SNF did not have nearly the same serious  
19 health consequences as your retrievable filters. True?

10:59:01 20 A It's not a retrievable filter, it's a permanent filter, so  
21 it is completely different.

22 Q Well, isn't that a little misleading, sir? Aren't all of  
23 your retrievable filters permanent filters first?

24 A Correct.

10:59:11 25 Q And they are all designed to be as permanent in a human



REDIRECT EXAMINATION - JOHN VAN VLEET

1 body as the Simon Nitinol filter. True?

2 A They're approved for both permanent and retrievable  
3 indications.

4 Q And they should be as safe as Simon Nitinol filter if a  
5 doctor or a patient chooses to have that device remain in them  
6 permanently. True?

7 A It wouldn't be safe if somebody tried to retrieve it.  
8 That's certainly the case.

9 Q No, sir. I said as a permanent device, it is required to  
10 be at least as safe and effective as the Simon Nitinol filter.  
11 True?

12 A It is -- it is required to be approved and tested for  
13 permanent and retrievable indication.

14 Q You mean cleared?

15 A Cleared.

16 Q Because approved -- because these devices were never  
17 approved by FDA; right?

18 A They're cleared by FDA.

19 MR. LOPEZ: That's all the questions I have at this  
20 time, Your Honor.

21 THE COURT: Redirect?

22 MR. NORTH: Yes, Your Honor.

23 R E D I R E C T E X A M I N A T I O N

24 BY MR. NORTH:

25 Q Mr. Van Vleet, in the ten years you worked with Bard, from

## REDIRECT EXAMINATION - JOHN VAN VLEET

11:00:11 1 2007 through 2017, did the FDA ever suggest to Bard that the  
2 company should recall the G2 product?

3 A No.

4 MR. NORTH: Thank you, sir. That's all I have.

## 11:00:26 5 RECROSS-EXAMINATION - JOHN VAN VLEET

## 6 R E C R O S S - E X A M I N A T I O N

7 BY MR. LOPEZ:

8 Q Sir, based on all of the evidence that Bard had, going  
9 back to the beginning of the G2 and its design flaws that the  
11:00:38 10 company recognized needed to be fixed, when the company  
11 determined it had an unacceptable risk of caudal migration  
12 that was further evidenced by the EVEREST study, and when the  
13 company saw the details in the Nicholson study, did the  
14 company ever sit down and think to themselves that maybe what  
11:00:58 15 they should do is to stop selling the G2 filter somewhere  
16 along that line?

17 A So many options were considered and that's why we've  
18 discussed it with FDA.

19 Q You discussed recalling this device with FDA?

11:01:11 20 A No. We discussed the allegations that were made by  
21 Nicholson.

22 Q And the obligation to stop selling a device is no one's  
23 obligation other than the company's. True?

24 A If it's determined through the internal processes that  
11:01:27 25 certain levels are reached, then there are procedures in place

## REDIRECT EXAMINATION - JOHN VAN VLEET

11:01:32 1 that drive us to do that; correct.

2 Q For example, if the device is not performing as  
3 represented, intended, and expected, it should be -- the  
4 company should stop selling it; correct?

11:01:42 5 A If a device is not performing, it possibly should.

6 Q Well, don't the regulations require you to stop selling a  
7 device once you've determined it's failing its own performance  
8 specifications for safety?

9 A I believe the regulation -- I'm not sure where you're  
11:02:02 10 going with this question, but I believe the regulations do  
11 require you to do certain things. You have to have a quality  
12 system that drives you to take action based on the complaint  
13 rates that are being reported and based on a host of other --

14 Q No, my question is simple. The regulations that you have  
11:02:21 15 to follow as a medical device company, if you know that you're  
16 selling an adulterated or a misbranded device, or it's not  
17 performing as you're representing it, you need to stop selling  
18 it. True?

19 A If it's adulterated or misbranded, it's illegal to be  
11:02:37 20 sold.

21 Q And you don't wait for FDA to make that determination; you  
22 need to make that determination yourself to protect people if  
23 that occurs. True?

24 A Your quality regulations would certainly drive you to take  
11:02:52 25 certain actions.

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:02:53 1 Q In other words, you don't -- 100 percent responsibility of  
2 whether or not the device -- you should stop selling the  
3 device is the company's responsibility?

4 A It's determined with the company and FDA. That's part of  
11:03:04 5 their request.

6 Q Sir, do you -- what are you saying?

7 A Any time that there's any recall that's done, we are to  
8 contact people in the district office and determine --

9 Q After you've made a decision that this device should be  
11:03:18 10 recalled or you should stop selling it, then you go tell the  
11 FDA you're taking that action. That's how it happens; right?

12 A Usually it's a negotiation.

13 Q Sir, you can make your own determination because it's your  
14 responsibility as to whether or not you should stop selling a  
11:03:32 15 device because it's adulterated or misbranded. Yes or no?

16 A Theoretically, a company can do that, yes.

17 Q Theoretically.

18 MR. LOPEZ: No further questions, Your Honor.

19 THE COURT: All right. You can step down, sir.

11:03:44 20 MR. CONDO: Your Honor, our next witness will be  
21 Dr. Audrey Fasching.

**AUDREY FASCHING, PH.D,**

23 called as a witness herein, after having been first duly sworn  
24 or affirmed, was examined and testified as follows:

11:04:45 25 MR. CONDO: May I proceed, Your Honor?

DIRECT EXAMINATION - AUDREY FASCHING, PH.D

THE COURT: You may.

D I R E C T E X A M I N A T I O N

BY MR. CONDO:

Q Good morning, Dr. Fasching.

I've addressed you as Dr. Fasching, you are not a medical doctor, are you?

A I am not.

Q Would you tell the ladies and gentlemen of the jury what your educational background is, please.

A Sure. I am -- I'm a metallurgical engineer. I received a BS in metallurgical engineering from Colorado School of Mines, and I worked for a few years and then went back to Colorado School of Mines, where I got my Ph.D.

Q And what was the discipline or disciplines in which you obtained your Ph.D?

A Sorry. I obtained my Ph.D in metallurgical and materials engineering.

Q And what is materials engineering?

A So materials engineering expands beyond just metals into ceramics and polymers and other materials.

Q Now, as a result of your education and your work experience, have you developed an expertise in the area of metallurgy?

A Yes, I have.

Q And materials science?

DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:06:10 1 A Yes.

2 Q And failure analysis?

3 A Yes.

4 Q Failure analysis of metals?

11:06:15 5 A Yes. Failure analysis of metals.

6 Q And does your experience in these areas include analysis  
7 of fractures in inferior vena cava Bard filters?

8 A Yes, it does.

9 Q Were you asked by Mr. North's office to examine  
11:06:35 10 Ms. Booker's G2 filter?

11 A I was.

12 Q And what were you asked to do with respect to Ms. Booker's  
13 G2 filter?

14 A I was asked to look at Ms. Booker's filter and evaluate it  
11:06:50 15 in terms of what types of fractures it had and possible causes  
16 of the fracture.

17 Q And have you done that?

18 A I have.

19 Q And have you also examined other Bard G2 filters for the  
11:07:04 20 same purpose?

21 A Yes, I have.

22 Q And have you also examined Bard Recovery filters for the  
23 same purpose?

24 A Yes, I have.

11:07:18 25 Q Have you examined all of the filters, the G2 and Recovery

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

1 filters, to determine whether there was a correlation or  
2 pattern to the fractures observed?

3 A I did examine them and compared the types of fractures and  
4 such to see if there was a pattern.

5 Q And were each of the filters that you examined retrieved  
6 from a patient?

7 A Well, I examined 30 explanted filters that were retrieved  
8 from a patient, and I also examined exemplar filters.

9 Q All right. Let's break down the filters that were  
10 retrieved from the 30 patients.

11 How many filters that were retrieved were Recovery  
12 filters that you examined?

13 A Okay. So I examined 13 Recovery filters, 14 G2 filters,  
14 and three G2X filters.

15 Q And was one of the G2 filters a filter retrieved from  
16 Ms. Booker?

17 A Yes.

18 Q Now, are you prepared to offer your expert opinions based  
19 on your examination of these 30 filters?

20 A Yes.

21 Q Will you tell the ladies and gentlemen of the jury the  
22 areas in which you are going to offer expert opinions.

23 A So I'm going to offer opinions in the area of the type of  
24 fractures that I observed and the possible causes of the  
25 fracture.

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:08:50 1 Q And you -- have you formed your expert opinions that  
2 you're prepared to offer to a reasonable degree of engineering  
3 and scientific certainty?

4 A Yes.

11:08:58 5 Q And have you formed your opinions based upon your total  
6 knowledge and experience, training, with respect to fracture  
7 analysis, metallurgical analysis, and materials science?

8 A Yes.

9 Q Lets talk, if we can, a little bit about your experience  
11:09:18 10 in conducting failure analysis investigations in medical  
11 devices. Do you have such experience?

12 A I do.

13 Q Can you describe for the ladies and gentlemen of the jury  
14 your experience in analyzing failures in medical devices.

11:09:33 15 A Sure. And as part of my current job I do a variety of  
16 failure analyses which include medical devices. And previous  
17 to -- I'm a consultant now. I worked for a company called  
18 Memory, which is a tube and wire manufacturer, they make  
19 Nitinol tube and wire, and some sheet, and do the first stage  
11:10:00 20 manufacturing of several types of medical devices.

21 Q And your time, your employment with Memory, how many years  
22 did you spend working with Nitinol products at Memory?

23 A I was at Memory for four years working with their Nitinol  
24 products.

11:10:17 25 Q And generally during that period of time, what kind of



## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:10:20 1 responsibilities did you have with respect to analyzing the  
2 performance of the Nitinol products produced by Memory?

3 A Well, so my role there was, I was their senior  
4 metallurgist, so I did a wide variety of things for them on  
11:10:37 5 Nitinol. Everything from training some of our customers on  
6 how to use and design with Nitinol to helping customers who  
7 were doing product development.

8 I was the person that, when we had a customer that,  
9 whether it was in their manufacturing process or they had  
11:10:59 10 purchased from us and then they were manufacturing, they would  
11 have an issue, I would often do the analysis on whatever that  
12 was. So they might have a fracture, or a corrosion issue  
13 or -- there were all kinds of different types of things that  
14 they would see.

11:11:19 15 I also did research and wrote papers and presented at  
16 professional conferences.

17 Q We'll talk about that a little bit. Let me move to  
18 teaching.

19 A Okay.

11:11:32 20 Q Do you have experience with teaching undergraduate  
21 students and graduate students in the subjects of metallurgy  
22 and materials science?

23 A Yes, I do. I've been an adjunct lecturer at Santa Clara  
24 University. I was there for about eight years. I taught in  
11:11:52 25 their mechanical engineering department. They don't have a

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

1 materials engineering department. And I taught their  
2 materials engineering courses, both undergraduate and graduate  
3 level.

4 Q Now, you mentioned briefly in passing in response to an  
5 earlier question that you've written articles and made  
6 presentations to professional organizations. Let's take those  
7 separately.

8 Have you made any presentations to professional  
9 organizations or groups where the subject matter of those  
10 presentations was relevant to the expert opinions that you  
11 have formed in this matter?

12 A Yes, I have.

13 Q And can you give the ladies and gentlemen of the jury an  
14 example, one or two examples, of the kinds of presentations  
15 you've made to professional organizations and the subject  
16 matters of those presentations.

17 A Sure. So for -- it's primarily Nitinol, but it's a shape  
18 memory. There's a professional group called SMST, which is  
19 Shape Memory Superelastic Technology, and I presented papers  
20 there. And I also -- also ASM, which is American Materials  
21 Society International. Now they have the International on the  
22 end. They also have a medical device conference that they  
23 have yearly, and I've presented papers there.

24 The subject matter of those papers were I -- one of  
25 them was fatigue. We were looking at rotating bending fatigue

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:13:37 1 life and -- and the effect of inclusions in the -- which is a  
2 naturally occurring impurity in Nitinol wire on fatigue life.

3 I looked at surface condition, the effect of surface  
4 condition, and how much -- basically corrosion. How much  
11:14:05 5 nickel, because nickel is an allergen. In fact, I'm allergic  
6 to nickel. When you're using a medical device that contains  
7 nickel, it's of concern that people aren't getting too much  
8 nickel. So we're looking at nickel leaching, which is nickel  
9 coming out and would enter the bloodstream, and we were doing  
11:14:29 10 that with a corrosion test. And we did that with different  
11 levels of strain and different surface conditions, and then we  
12 would corrode it for six weeks, and then we were testing for  
13 nickel in the liquid on that.

14 Q Thank you.

11:14:47 15 Now, you mentioned an organization. I wrote down  
16 Shape Memory Superelastic Technology.

17 A Yes.

18 Q What is that organization and what is its primary focus?

19 A Well, so it's a professional society. It used to be its  
11:15:08 20 own entity, but it's been absorbed now by ASM, which is kind  
21 of the larger professional materials society, but they still  
22 have regular conferences. It's the large -- it is an  
23 international conference, so it's held worldwide, and they  
24 alternate between Europe, the United States, and Asia, and  
11:15:34 25 they rotate back and forth.

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:15:37 1 Q Is one of the subjects or focus of that organization  
2 Nitinol products?

3 A Primarily. So for shape memory and superelastic  
4 materials, primarily you're talking about Nitinol. There's  
11:15:50 5 some copper alloys that also fall in there, and there are  
6 polymers -- some polymers exhibit shape memory and  
7 superelastic properties.

8 Q Does Nitinol have shape memory and superelastic  
9 properties?

11:16:09 10 A Yes, it does.

11 Q Can you describe each of those properties for the ladies  
12 and gentlemen of the jury. Let's start with superelastic.

13 A Okay. So Nitinol is a superelastic material. It's metal.  
14 It is 50 percent nickel, 50 percent titanium, approximately.  
11:16:28 15 It's slightly off that, but not significantly.

16 So superelasticity, the elastic means that you can  
17 bend it and it will return to its shape with no permanent  
18 deformation. And most metals don't have a lot of elasticity.  
19 So, for instance, like if you take a paperclip and you were to  
11:16:54 20 bend it, you wouldn't have to bend it very far and it would  
21 stay open however much you bent it. It doesn't return to its  
22 shape.

23 If we were to take that same paperclip shape and make  
24 it out of Nitinol, we could open the paperclip and let it go  
11:17:10 25 and it would return to its original shape, its original

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:17:14 1 paperclip shape. And that's the superelastic property.

2 Q Now, what is the shape memory characteristic of Nitinol?

3 A Okay. Well, so it also has a shape memory characteristic  
4 that makes it unique in that -- and useful for medical

11:17:38 5 devices, like IVC filters, in that you can -- what they do is  
6 they make it cold and they squeeze it down so it fits in a  
7 tube, a delivery tube, and then they can insert it through the  
8 femoral artery up into the place the doctor inserts it. And  
9 when he deploys it, that particular alloy, and there's only  
11:17:57 10 one particular alloy that is used for medical devices, and  
11 it's designed that it will return to its shape at body  
12 temperature.

13 So it's inserted -- you know, it's been squeezed down  
14 flat, and it's inserted into the body, and because it's at the  
11:18:14 15 correct temperature, it opens up. So in the case of the IVC  
16 filter, it will open up like an umbrella in place. It  
17 remembers the shape that it was programmed into.

18 Q And is that alloy the alloy that is used in the production  
19 the Recovery and G2 IVC filters?

11:18:35 20 A Yes.

21 Q And how is the memory programmed into, I think your words,  
22 into the filter?

23 A Yeah. So during the manufacturing process, what you do,  
24 and sometimes you can do it in one step, most of the time it's  
11:18:51 25 multiple steps, but they will take the shape and they attach

## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:18:58 1 it to usually a steel or high temperature fixture, and then  
2 they'll heat treat it. And when you heat treat it correctly,  
3 then it will remember the shape.

4 Q And then, when it's chilled, it's inserted into the  
11:19:17 5 deployment sheath in the case of an IVC filter?

6 A Yeah. They squeeze it down, um-hmm.

7 Q When the filter is then deployed in the IVC, does the body  
8 temperature affect the filter?

9 A When the filter is deployed -- well, so -- so when it --  
11:19:39 10 yeah. So when it reaches the temperature, which is your body  
11 temperature for that particular alloy, it will open up into  
12 the same shape that it was at the end of the manufacturing  
13 process after the heat treatment.

14 Q Right.

11:19:55 15 I jumped over your employment. Where are you  
16 employed?

17 A I work for a small company called Anamet. It is an  
18 engineering consulting company.

19 Q What is your title or position with Anamet?

11:20:08 20 A I'm a senior materials engineer.

21 Q Are you an owner or an employee of the company?

22 A I'm an employee.

23 Q Okay. And as an employee of the company, does the company  
24 bill Mr. North's office for any services you perform in  
11:20:23 25 connection with your investigation?

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11:20:25 1 A Yes.

2 Q And what hourly rate, if you know, does Anamet charge for  
3 your services?

4 A \$375 an hour.

11:20:36 5 Q And does that change if you're here testifying today?

6 A No.

7 Q Does your compensation depend at all on the volume of  
8 billings that are generated by Anamet for your work?

9 A No.

11:20:50 10 Q Do you know how much Anamet has billed for your services  
11 over the period of time that you've been involved in the study  
12 of Bard IVC filters?

13 A Yeah, I -- it's been approximately \$300,000 over the last  
14 seven years.

11:21:05 15 Q Thank you.

16 Now, as part of forming your expert opinions, have  
17 you viewed the deposition of Dr. McMeeking?

18 A Yes.

19 Q And have you reviewed the deposition of Mr. Andre  
20 Chanduszko?

21 A Yes.

22 Q And have you reviewed the deposition of Mr. Rob Carr?

23 A Yes.

24 Q Is that a complete list of the depositions you have  
11:21:29 25 reviewed as part of your study?

DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:21:30 1 A No.

2 Q And have you, as part of forming your expert opinions,  
3 also reviewed various NMT and Bard test reports and lab  
4 notebooks involving fatigue testing?

11:21:41 5 A Yes.

6 Q And have you, as part of forming your expert opinions,  
7 conducted an independent study of publicly available  
8 information of the sort customarily relied upon by experts in  
9 your field?

11:21:57 10 A Yes.

11 Q Did you document the physical condition of Ms. Booker's  
12 filter when you examined it?

13 A I did.

14 Q And did you photograph the filter?

11:22:10 15 A I did.

16 Q And have you prepared a demonstrative exhibit to assist  
17 you in explaining to the jury the position of the fractured  
18 arm and leg of the filter?

19 A Yes, I have.

11:22:22 20 Q And does, in fact, the demonstrative exhibit show the  
21 fractured arm and leg?

22 A Yes.

23 MR. CONDO: May we have Exhibit 7465, please.

24 THE WITNESS: I see it here. Okay.

25



## DIRECT EXAMINATION - AUDREY FASCHING, PH.D

11:22:40 1 BY MR. CONDO:

2 Q Would you like the paper copy?

3 A No, I'm fine. I just wasn't sure where it was going to  
4 come.

11:22:47 5 Q Can you identify this? Just describe it generally.

6 A Okay. So this is Ms. Booker's G2 filter. These are  
7 photographs that I took when they were received at my office  
8 and after I had unpacked them.

9 Q And would this exhibit assist you in explaining your  
11:23:08 10 observations of the filter when received to the ladies and  
11 gentlemen of the jury?

12 A Yes.

13 MR. CONDO: Your Honor, we would offer Exhibit 7465  
14 as a demonstrative exhibit.

11:23:22 15 THE COURT: Any objection?

16 MR. O'CONNOR: Not as a demonstrative.

17 THE COURT: All right. You may use it.

18 MR. CONDO: Thank you, Your Honor.

19 May we publish?

11:23:33 20 THE COURT: Yes.

21 BY MR. CONDO:

22 Q Doctor, can you explain to the jury, using this exhibit,  
23 the condition of the filter when you received it for analysis?

24 A Sure. So I received it. And when I receive it, I take  
11:23:56 25 note of the pieces that are there. There was one fractured

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1 leg segment with the major filter, and when I examined it, I  
2 count the arms and the legs, which are in the -- if I touch  
3 this, is this how it works? Yeah. So -- oh, sorry.

4 So the arms and the legs were right next --

11:24:24 5 Q Let me stop you. And let's talk about the photograph on  
6 the left side first.

7 A Okay. The left side.

8 Q What is important in that photograph as it affects your  
9 expert opinions?

11:24:40 10 A Well, that there's an arm and a leg missing and a leg  
11 segment there. From the majority filter there was an arm and  
12 a leg missing.

13 Q So you had a filter and one piece of a leg; correct?

14 A Yes.

11:24:58 15 Q If you put the piece back to the filter, did that make the  
16 filter complete in the sense that it would be a full G2  
17 filter, or was there something missing?

18 A No, there was something missing. So another aspect that I  
19 do is I take measurements of the segments that are there, and  
11:25:19 20 there's a -- there was a small segment of the leg that was  
21 still attached to the filter, and you can kind of see it on  
22 the second picture, where the long red arrow is pointing.  
23 There's just a tiny little piece.

24 And then, I measured the leg segment that was  
11:25:38 25 fractured off, and the whole leg span is supposed to be

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1 40 millimeters, and that didn't equal 40 millimeters. So  
2 there was about 13 millimeters missing, or about a half an  
3 inch.

4 Q All right. Now, this may be a little difficult to explain  
5 without these visual demonstrative aids, but if you look at  
6 the photograph on the left, the leg fracture segment --

7 A Um-hmm.

8 Q -- and then you look at the photograph on the right and  
9 you have a red arrow that says L1 fractured, and it points to  
10 a very small little piece of the filter leg; correct?

11 A Yes.

12 Q Now, does the fracture end of the leg on the left side  
13 match up with the fracture fragment on the right photograph?

14 A No. They did not match.

15 Q Explain why not.

16 A Okay. Without looking at the photographs yet?

17 Q Any way you want to.

18 A Okay. Well, so when you're looking at fracture surfaces,  
19 it's is always nice if you have both sides, because sometimes  
20 you can see something on one side that you don't. But the  
21 clue to whether you have -- whether -- they need to match up,  
22 and it's like they should be mirror images of each other; you  
23 pull them apart and they're mirror images.

24 When I -- and I put these in a -- so I take these  
25 photographs, and then I put them in a scanning electron

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11:27:28 1 microscope to look at the fracture surfaces. That's where I  
2 do that.

3 And it was pretty obvious that they were not mating  
4 halves. So, again, why there's a segment missing in between  
11:27:42 5 those two pieces, they were never connected.

6 Q And did you receive any fractured arm segment as part of  
7 your receipt of this filter?

8 A I did not.

9 MR. CONDO: You can take that down. Thank you.

11:28:00 10 BY MR. CONDO:

11 Q Let's turn to the details of your examination of each of  
12 the retrieved filters.

13 Can you tell the ladies and gentlemen of the jury  
14 whether you analyzed each filter for the number of fractures  
11:28:15 15 that were observable?

16 A Yeah. So similarly, when I would receive a fractured  
17 filter, I would photograph it, count the number of arms and  
18 legs that were there, take measurements, record where the  
19 fractures occurred, and that type of information.

11:28:40 20 Q And did you also analyze each filter for the type of  
21 fractures?

22 A I did.

23 Q And did you analyze each filter to determine the location  
24 of the fractures?

11:28:50 25 A I did.

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11:28:54 1 Q Did all of the retrieved filters that you examined have  
2 fractures?

3 A All of the retrieved filters did not have fractures. Two  
4 of them did not have fractures.

11:29:06 5 Q How many different fractures did you examine?

6 A So of the 30 filters that I looked at, there were 52 arm  
7 fractures and seven leg fractures, not including Ms. Booker's  
8 leg.

9 Q And why didn't you include Ms. Booker's leg fractures in  
11:29:34 10 your count of the total number of leg fractures?

11 A Because every other filter that I had only had one leg  
12 fracture. No other filter that I looked at had two fractures  
13 on the same leg.

14 Q So this was a unique condition for Ms. Booker's filter?

11:29:54 15 A Yes. Two fractures on one strut was a unique condition.

16 Q And there was no other filter in the 29 other retrieved  
17 filters that demonstrated a similar unique characteristic?

18 A No.

19 MR. O'CONNOR: Objection. Irrelevant, Your Honor.

11:30:13 20 THE COURT: Overruled.

21 BY MR. CONDO:

22 Q Now, if we take away Ms. Booker's filter out of the total,  
23 we have 51 fractured arms; correct?

24 A Yes.

11:30:25 25 Q In how many explanted or retrieved filters? 29?

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11:30:31 1 A 29.

2 Q Did you determine for those 51 arm fractures from the 29  
3 filters the direction of fracture?

4 A So that was one of the parameters that I measured and  
11:30:49 5 recorded, yes. And --

6 Q And what results did you obtain?

7 A Yeah. So I kind of recorded that generally by whether  
8 they were fractured by -- well, they all fractured by bending.  
9 And whether they were, at the time that the crack formed,  
11:31:13 10 propagated, and grew, whether they were bending in towards the  
11 sented center of the filter or out towards the outside of the  
12 filter. And of the 51 arms, there were 29 that were bending  
13 towards the inside and 19 that were bending to the outside.  
14 And then there were two that were really just going sideways.

11:31:40 15 Q What do you mean going sideways?

16 A Well, so, what I tried to do is the filter down is round.  
17 I drew a circle and drew a line, a diameter across the center.  
18 And so if the fractures initiated towards the outside and were  
19 bending in, I counted that as outside. On the other half, if  
11:32:07 20 they were somewhere around -- generally bending towards the  
21 outside of the filter, I counted that as bending outside  
22 rather than inside. And then, the two other ones were kind of  
23 right on that line, just bending basically through the other  
24 arms and legs on the filter.

11:32:32 25 Q Now, I think you said you also examined exemplar Recovery

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11:32:38 1 and G2 filters; correct?

2 A Yes.

3 Q And why did you examine exemplar filters?

4 A Well, so the useful reason to examine an exemplar is so  
11:32:50 5 you have a good idea of what the condition of the filter was  
6 after manufacturing, but prior to it being implanted.

7 Q And did that help you determine dimensionally whether you  
8 had complete filters, for example, when you examined a  
9 retrieved filter?

11:33:12 10 A Yes. Certainly. So I was able to, you know, look at  
11 basic measurements and geometry of an exemplar filter and  
12 understand better what the explanted filter should look like  
13 or looked like before it was implanted.

14 Q And did you tally the total number of arm fractures that  
11:33:40 15 were observed on the Recovery filters and compare those with  
16 the total number of arm fractures on the G2 filters?

17 A I did.

18 Q And what results did you get when you made that  
19 comparison?

11:33:54 20 A So --

21 MR. O'CONNOR: Objection. Your Honor, this is not  
22 within her report, any type of comparison.

23 THE COURT: Is this in the report, Mr. Condo?

24 MR. CONDO: It is. It is in appendix A, I believe,  
11:34:07 25 where she has a complete total --

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11:34:10 1 THE COURT: Would you show those to me, please.

2 If you want to stand up, ladies and gentlemen, feel  
3 free.

4 (Bench conference as follows:)

11:34:36 5 THE COURT: So the question is did she compare total  
6 number of Recovery arm filters to the total number G2 arm  
7 fractures.

8 MR. CONDO: All of the fractures are totaled here and  
9 here by G2 and by Recovery.

11:34:51 10 MR. O'CONNOR: In her opinions she never did a  
11 comparative analysis. She shows a table in each, but she  
12 never stated an opinion that she has compared them.

13 And another thing, she has never in her specific --  
14 case-specific opinion indicated that she compared the Booker  
11:35:08 15 to any of these other filter --

16 THE COURT: Well, where are you going with this,  
17 Mr. Condo? So she says, yes, I compared. What's your next  
18 question?

19 MR. CONDO: What were the number of fractures for  
11:35:21 20 each.

21 THE COURT: And what's wrong with that if it's right  
22 here in the table?

23 MR. O'CONNOR: Well, she hasn't gone and done a  
24 comparative analysis. She has two separate tables, but she's  
11:35:32 25 never written in the report, so they never gave us notice that



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11:35:34 1 somehow she was going to lead this jury to believe that the  
2 filter, the G2, has a less fracture rate than the Recovery.  
3 That's the inference.

4 THE COURT: Are you going to do more than ask her for  
11:35:46 5 the numbers?

6 MR. CONDO: Not at this point. No.

7 THE COURT: Well, she can clearly testify what the  
8 numbers show. They're in the table, they're in the report.  
9 If you go beyond that and ask her to explain why or what she  
11:35:56 10 concludes from it and you don't think it's in a report, you  
11 can object at that point. But I'm going to overrule this  
12 objection because the numbers are in the tables.

13 MS. SMITH: There's a stipulation, because it  
14 includes other lawsuits these filters are from --

11:36:12 15 MR. O'CONNOR: That's fine. They can put that in  
16 there. I understand your point. But what he can't do is now  
17 try to have her say that somehow the Booker filter was  
18 different than these other fractures, which they trying to do.  
19 That has never been --

11:36:28 20 THE COURT: That has not been asked.

21 MR. O'CONNOR: Pardon me?

22 THE COURT: That has not been asked.

23 MR. O'CONNOR: He got close to it before.

24 THE COURT: Are you going to ask her to compare  
11:36:34 25 Booker to others?

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11:36:36 1 MR. CONDO: Eventually, yes. I'll lay all the  
2 foundation --

3 THE COURT: Is that in the report?

4 MR. O'CONNOR: Where? Where is it in the Booker  
11:36:43 5 report?

6 MR. CONDO: Can I get my outline?

7 THE COURT: Yeah, that's fine.

8 Don't be reading his notes.

9 MR. O'CONNOR: Pardon me?

11:37:19 10 THE COURT: Don't be reading his examination notes.

11 MR. O'CONNOR: Oh. Sorry.

12 MR. CONDO: Got to find out where the thing is.

13 THE COURT: Well, let me ask you this question,  
14 Mr. Condo. How long do you think you're going to take with  
11:37:41 15 this witness?

16 MR. CONDO: Oh, I'm going to go to the lunch hour.

17 THE COURT: Then let's deal with this without keeping  
18 the jury waiting. You can show that to me at the lunch hour  
19 so we don't keep the jury waiting.

11:37:53 20 MR. CONDO: I will.

21 (Bench conference concludes.)

22 THE COURT: Thank you, ladies and gentlemen.

23 BY MR. CONDO:

24 Q I think I was asking you to tell the ladies and gentlemen  
11:38:31 25 of the jury the results when you tallied up the total arm

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1 fractures on the Recovery filter and compared them to the  
2 total arm fractures you observed on the G2 filter.

3 THE COURT: You're asking just for the numbers?

4 MR. CONDO: Just for the numbers.

5 THE COURT: All right.

6 THE WITNESS: Okay. So there were 36 arm fractures  
7 total on Recovery. And on G2, I looked at -- I looked at 16  
8 G2 and G2X filters and -- that's how I have it remembered.  
9 And there were 15 arm fractures.

10 BY MR. CONDO:

11 Q Thank you.

12 Now, let's talk about the methodology and the  
13 processes that you used in your examination of these filters.

14 Tell the ladies and gentlemen what you did when you  
15 would receive a filter, whether it was Ms. Booker's or any of  
16 the other 29 retrieved filters. What was this process that  
17 you went through and what processes did you utilize?

18 A Okay. So you already saw the initial photograph. That --  
19 photographs that I would take. I would receive the filters,  
20 usually take it at a couple different of angles, make sure I  
21 could have a good picture that I could mark where the arms and  
22 legs were.

23 I would use a stereomicroscope, which is an optical  
24 microscope, to do the measurements on the fractures, arms and  
25 legs. And that's a calibrated microscope we put in a scale

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11:40:18 1 and -- before we do measurements.

2 And then -- and then, finally, to examine the  
3 fracture, the actual fracture surfaces and just the general  
4 kind of surface condition of the filter, I put it in an  
11:40:33 5 electron microscope, scanning electron microscope, or an SEM.

6 Q And, generally, how would these retrieved filters come to  
7 you?

8 A So the retrieved filters were sent to me by third party  
9 various --

11:40:56 10 Q Did they come all together or over period of time?

11 A No. Over a seven-year period of time.

12 Q So as each one was received, you would use the  
13 stereoscopic microscope?

14 A Stereoscope, yeah.

11:41:10 15 Q Stereoscope. And then utilize an SEM or scanning electron  
16 microscope?

17 A Yes.

18 Q Is the utilization of a scanning electron microscope a  
19 generally accepted process that's used by metallurgists in the  
11:41:27 20 analysis of fractures?

21 A Yes. It is widely used and widely accepted.

22 Q To your knowledge, based upon your review of his  
23 deposition testimony and reports, did Dr. McMeeking examine  
24 any filters, IVC filters, using a scanning electron  
11:41:46 25 microscope?

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11:41:47 1 A He did not.

2 Q Did you do any destructive testing as part of your  
3 examination of any of these filters?

4 A No, we did not.

11:41:55 5 Q Why not?

6 A Well, you're -- you're -- without permission, since this  
7 is a legal case, I can't legally do any destructive testing.  
8 So --

9 Q But without doing the destructive testing, are you still  
11:42:13 10 confident that you have enough information to form your  
11 opinions in this matter to a reasonable degree of engineering  
12 and metallurgical scientific certainty?

13 A Yes.

14 Q Okay. Now, have you formed an opinion to a reasonable  
11:42:24 15 degree of engineering and scientific certainty as to the type  
16 of the three fractures that Ms. Booker's filter exhibited?

17 A Yes.

18 Q And let's start first with the leg fractures. What type  
19 of fracture did you observe?

11:42:44 20 A The leg fractures were both bending fatigue.

21 Q And what is bending fatigue?

22 A Well, so, fatigue is cyclic loading usually at low  
23 stresses, so you -- and you're cycling it. Bending fatigue  
24 means you're bending in one direction and back to neutral, one  
11:43:04 25 direction and back to neutral.

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11:43:09 1 Q And let's talk, then, about your opinion with respect to  
2 the type of fracture exhibited on Ms. Booker's filter at the  
3 arm. Did you form an opinion about that type to a reasonable  
4 degree of engineering and scientific certainty?

11:43:25 5 A Yes.

6 Q And what is your opinion about the type of that fracture?

7 A I believe that was also bending fatigue.

8 Q And where did the arm fracture occur?

9 A So in Ms. Booker's filter, the arm fracture occurred  
11:43:40 10 inside the sleeve. So the wires come out of the sleeve and  
11 the fractures surface was actually inside the sleeve.

12 Q Was it fully visible to you, the fracture surface?

13 A It was not fully visible.

14 Q What was preventing full visibility of the fracture  
11:44:02 15 surface of the arm fracture?

16 A So really two things. When you're using an electron --  
17 scanning electron microscope, you're bombarding the surface  
18 with electrons, and when you're trying to shoot electrons into  
19 a little tube onto a fracture surface in there and get those  
11:44:25 20 electrons to bounce back and collect, basically you get a  
21 poorer signal, so it was more difficult to image, which was  
22 complicated also by the fact that it had some biological  
23 debris still because -- probably, again, because it was inside  
24 the sleeve, difficult to clean off. So the entire fracture  
11:44:47 25 surface was not visible.

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11:44:49 1 Q And did you photographically document with SEM photographs  
2 the condition of the fracture face of the arm?

3 A Yes, I did.

4 Q And did you prepare a demonstrative exhibit to assist the  
11:45:04 5 ladies and gentlemen of the jury in explaining what you  
6 observed on the fracture face?

7 A Yes.

8 Q And would that assist you, would that demonstrative assist  
9 you in explaining?

11:45:19 10 A Yes.

11 Q Okay.

12 MR. CONDO: May we have 7467, please.

13 THE WITNESS: Yeah. So --

14 BY MR. CONDO:

11:45:28 15 Q That's no question. Just give me a second.

16 A Oh, sorry.

17 Q You're more efficient than I am.

18 Is this the demonstrative exhibit that you prepared?

19 A Yes, it is.

11:45:39 20 Q And did you place on the demonstrative the arrows and the  
21 descriptions of the fracture face surfaces?

22 A I did.

23 MR. CONDO: Your Honor, we would offer 7467 as a  
24 demonstrative exhibit.

11:45:54 25 MR. O'CONNOR: No objection, Your Honor, for the

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11:45:57 1 demonstrative.

2 THE COURT: All right. You may display it as a  
3 demonstrative exhibit.

4 MR. CONDO: Thank you, Your Honor.

11:46:12 5 BY MR. CONDO:

6 Q Do you have a good image on the screen in front of you?

7 A Yes.

8 Q Let's talk about the image on the left.

9 A Okay.

11:46:18 10 Q What are we seeing on the image on the left?

11 A Well, so this is a lower magnification view of the arm.  
12 I've labeled that the darker -- the darker part of the  
13 fracture surface is the biological debris, and I labeled that.  
14 You can see the fracture surface. And I guess I'll draw this  
11:46:46 15 part right here. This is the sleeve, the edge of the sleeve.  
16 I think you can see that it's set down in there, inside that  
17 sleeve.

18 Q And what is the sleeve of? Is that the cap or the tip of  
19 the filter?

11:47:03 20 A Yeah, the sleeve or the cap, the top of the filter there,  
21 um-hmm.

22 Q Did any of the other filters that you examined have a  
23 fracture occurring in this same precise location?

24 A Ms. Booker's filter was the only filter that had an arm  
11:47:23 25 fracture inside the sleeve like that.



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11:47:30 1 Q You talked about lower magnification. What was the  
2 magnification of the photograph on the left?

3 A So you can see on the bottom bar there, it was 150X.

4 Q And now let's move to the right-hand photograph. What  
11:47:48 5 image -- what does that image depict?

6 A Well, so this is a closer up image of the fracture  
7 surface. And when you're looking at fracture surfaces and  
8 trying to figure out what happened, you look for specific  
9 features on the fracture surface.

11:48:04 10 This one is a little trickier because part of it is  
11 covered up, but there are some lines, which I can show you  
12 better on a different photograph, called -- that we call river  
13 patterns or river lines. And if you follow those lines back,  
14 you'll see where the fracture initiation is.

11:48:33 15 In this case, it happens so -- I guess I'll draw  
16 these on. These are all kind of the river lines. You can see  
17 them there. And if they point back, the fracture initiation  
18 is going to be somewhere back here. We can't really see  
19 because it's covered up.

11:48:57 20 Q Now, in your analysis, even though there was some  
21 obstruction due to both the position of the filter and the  
22 biological material, was there still enough evidence to allow  
23 you to determine the type of the fracture?

24 A Yes, there was, um-hmm.

11:49:17 25 Q And remind the ladies and gentlemen of the jury what type

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1 of fracture are we looking at?

2 A This, again, was a bending fatigue fracture.

3 Q Thank you.

4 MR. CONDO: We can take that down, please.

5 BY MR. CONDO:

6 Q Now, do you have an opinion to a reasonable degree of  
7 engineering and scientific certainty as to the likely causes  
8 of the fractures in Ms. Booker's filter?

9 A In Ms. Booker's filter, I think the likely cause --

10 MR. O'CONNOR: Objection, Your Honor. Beyond the  
11 report.

12 THE COURT: Is that in the report?

13 MR. CONDO: It is, Your Honor. Section 5.2, page 16.

14 THE COURT: Do you have another copy of the report?

15 MR. O'CONNOR: The Booker report.

16 MR. CONDO: Yes.

17 MR. NORTH: Jim, I have one.

18 MR. CONDO: May I approach, Your Honor? I have two;  
19 one that's highlighted and one that's not.

20 THE COURT: All right. Yes. Please.

21 5.2, page 16?

22 MR. CONDO: Not on this report. There's another  
23 report. There are actually three reports.

24 THE COURT: Okay. Well, I need the one where it's  
25 disclosed.

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11:50:58 1 MR. CONDO: What's that?

2 THE COURT: I need the one where it's disclosed.

3 MR. CONDO: It should be here.

4 THE COURT: I have 5.2 on a page 16. That's what I

11:51:06 5 should be looking at; right?

6 MR. CONDO: Now, if Your Honor will allow me, if you

7 look at the July 31 report.

8 THE COURT: I've got two April 14 reports.

9 MR. CONDO: Didn't I give you a July 31 report?

11:51:41 10 THE COURT: You just handed me an April 14th report.

11 MR. CONDO: I'm sorry. It should be in the third

12 paragraph or fourth paragraph, I believe, of the July report.

13 THE COURT: So should I disregard --

14 MR. CONDO: Disregard my earlier cite.

11:52:11 15 THE COURT: Okay. Just one second.

16 I don't see anything in the fourth paragraph about

17 cause of fracture.

18 MR. CONDO: I think it talks about bending --

19 THE COURT: I see in the third paragraph. Hold on a

11:52:45 20 second.

21 MR. CONDO: I'm sorry.

22 THE COURT: I see where it said bending fatigue. Is

23 that what you're eliciting?

24 MR. CONDO: Yes.

11:53:18 25 THE COURT: Well, that's clearly in the report. That

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1 objection is overruled with respect to bending. Reask the  
2 question, please.

3 MR. O'CONNOR: If I may, that question was already  
4 asked and answered. The question he asked was different as to  
11:53:28 5 what --

6 THE COURT: That's why I'm having him reask the  
7 question.

8 MR. O'CONNOR: Thank you.

9 BY MR. CONDO:

11:53:33 10 Q Well, let me approach this, if I can, a little different  
11 way.

12 MR. CONDO: May I have the report back, Your Honor?

13 THE COURT: You may.

14 BY MR. CONDO:

11:54:08 15 Q The -- if we look at --

16 MR. CONDO: Can we put that last exhibit up, please,  
17 7467. The demonstrative.

18 May we publish, Your Honor?

19 THE COURT: You may.

11:54:28 20 BY MR. CONDO:

21 Q Now, looking at either of these two photographs, I asked  
22 you before about the type of the fracture, and you told me  
23 that it was bending fatigue?

24 A Um-hmm. Yes, I did.

11:54:50 25 Q And I asked you whether or not it is -- there is

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1 sufficient information in the report to determine whether  
2 bending fatigue was, in fact, the mode of fracture. In other  
3 words, even with the biological materials.

4 A Sufficient information on the fracture surface. Yes.

11:55:12 5 Q Now, can you tell the ladies and gentlemen of the jury,  
6 using either of these two photographs, where the point of  
7 initiation of the fracture was.

8 A Yeah. I had that marked up there but, again, you -- I  
9 guess I'll draw them on again. To determine a location of  
11:55:43 10 fracture initiation on a Nitinol fatigue fracture surface,  
11 we're going to look for these features called river patterns.  
12 And I think you can see them there. So they follow -- and you  
13 follow them back. Many fatigue fractures will initiate on the  
14 outside surface. And the direction of the river patterns  
11:56:20 15 point back to the initiation site, which is going to be at the  
16 edge.

17 I'll put it on this one, actually. Right around  
18 where I put that dot underneath the biological debris, judging  
19 from the river patterns there.

11:56:40 20 Q Now, do you have an opinion to a reasonable degree of  
21 engineering and scientific certainty as to whether the cause  
22 of the fracture in the arm in Ms. Booker's filter is  
23 consistent with the causes of the arm fractures noted in the  
24 other 29 filters that you examined?

11:57:05 25 MR. O'CONNOR: Objection. Nondisclosure. Nowhere in

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11:57:07 1 the report.

2 THE COURT: All right. Rather than keep you waiting  
3 while we have this discussion, we're going to break for lunch,  
4 ladies and gentlemen. We'll plan to resume at 1 o'clock.

11:57:15 5 We'll excuse the jury at this time.

6 (The jury exited the courtroom at 11:57.)

7 THE COURT: You can go ahead and step down. Thanks.

8 Mr. Condo?

9 MR. CONDO: Yes.

11:57:45 10 THE COURT: Would you point out in the report where  
11 the -- you can do it from there -- where the disclosure is of  
12 the different -- well --

13 MR. CONDO: The 29?

14 THE COURT: -- whether the Booker fracture is  
11:57:58 15 different from the 29. Where is that?

16 MR. CONDO: In the April 14, 2017, report, there is a  
17 section 5.2 that talks about the 29 arm filters, and says that  
18 "the variety of fracture characteristics" --

19 THE COURT: Where are you reading?

11:58:28 20 MR. CONDO: Page 16.

21 THE COURT: I've got it in front of me.

22 MR. CONDO: Section 5.2, the last sentence on the  
23 first paragraph.

24 THE COURT: Okay.

11:58:43 25 So what does that sentence say about comparing

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11:58:46 1 Ms. Booker's fracture --

2 MR. CONDO: Well, that's what I'm asking her, if she  
3 can determine from this evidence whether it's consistent with  
4 her observations here. There is no specific statement in her  
11:58:56 5 Booker specific July 31, 2017, report that says that the  
6 loading here was the same as the loading observed in the other  
7 29. But the fracture evidence is the same.

8 THE COURT: I'm not tracking that. This sentence you  
9 just read, tell me what you think that discloses that she's  
11:59:21 10 going to say.

11 MR. CONDO: It's going to -- it does not disclose  
12 anything about the Booker filter.

13 THE COURT: Okay.

14 MR. CONDO: This deals with 29, not including Booker.

11:59:35 15 THE COURT: Okay.

16 MR. CONDO: Booker was different.

17 And what I'm trying to do is establish that the 29  
18 exhibited all of the same fracture patterns that the Booker  
19 filter demonstrated.

11:59:48 20 THE COURT: Where is that statement disclosed?

21 MR. CONDO: That is not in anything that has been  
22 written specific to Booker.

23 THE COURT: Okay. I'm going to sustain the  
24 objection.

11:59:59 25 MR. CONDO: Thank you, Your Honor.

12:00:00 1 All right. You're going to make the motion tomorrow  
2 afternoon; right? Is that what we agreed on, Mr. North?

3 MR. NORTH: Yes, if that's okay with the Court.

4 THE COURT: Okay. We'll see you after the lunch  
12:00:10 5 hour, then. Thank you.

6 (Recess taken at 12:00.)

7 (End of a.m. session transcript.)

8 \* \* \* \* \*



C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 26th day of March, 2018.

s/ Patricia Lyons, RMR, CRR  
Official Court Reporter